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(54) Title: **INSERTION DEVICE FOR AN INSERTION SET AND METHOD OF USING THE SAME**

(57) Abstract: An insertion device and insertion set. The insertion device for inserting at least a portion of at least one piercing member of an insertion set through the skin of a patient includes a device housing, a carrier body and a driver. The carrier body is slidably received within the device housing for movement between an advanced position and a retracted position. The carrier body also includes a receiving structure to support the insertion set in a position with the at least one piercing member oriented for insertion through the skin of the patient at a predetermined or variable angle relative to the skin of the patient upon movement of the carrier body from the retracted position to the advanced position. The driver is operatively coupled between the device housing and the carrier body to urge the carrier body from the retracted position toward the advanced position to place at least a portion of the at least one piercing member of the insertion set thorough the skin of the patient to install the insertion set to the patient. The receiving structure of the carrier body is removable from the insertion set while maintaining the installation of the insertion set to the patient.

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## Insertion Device For An Insertion Set And Method Of Using The Same

5    RELATED APPLICATIONS:

This application is a continuation-in-part of U.S. Patent Application Serial No. 09/215,356, filed December 18, 1998, which is a continuation-in-part of U.S. Patent Application Serial No. 09/002,303, filed December 31, 1997, both of which are herein specifically incorporated by reference.

10

FIELD OF THE INVENTION

This invention relates generally to an insertion device for automatic placement of an insertion set through the skin of a patient, and in particular embodiments to a compact and easily operated insertion device for placement of  
15    an insertion needle of a subcutaneous insertion set or the like through the skin of a patient with a controlled force and insertion speed by the patient.

BACKGROUND OF THE INVENTION

Medical needles are widely used in the course of patient care and  
20    treatment, particularly with respect to the delivery of selected medications to a patient. In one common form, hollow hypodermic needles are employed for transcutaneous delivery of a selected medication from a syringe or the like. In another common form, insertion needles are employed for transcutaneous placement of a soft and relatively flexible tubular cannula, followed by insertion  
25    needle removal and subsequent infusion of medical fluid to the patient through the cannula. More recently, insertion needles have also been used for transcutaneously placing other medical devices such as a subcutaneous sensor for monitoring specified patient parameters, such as blood glucose level.

In certain medical treatment regimens, it may be necessary or desirable for  
30    the patient to transcutaneously place the medical needle. For example, diabetic patients frequently self-administer insulin injections or periodically place a subcutaneous insertion with a cannula for subsequent programmable delivery of insulin by means of a medication infusion pump of the general type described in

U.S. Patent 4,685,903. Such subcutaneous insertion sets are disclosed, for example, in U.S. Patents 4,755,173; 5,176,662; and 5,257,980 which are incorporated by reference herein. Diabetic patients may also use a subcutaneous  
5 insertion set to periodically place a transcutaneous glucose sensor wherein such sensor insertion sets are disclosed, for example, In U.S. Patents 5,390,674; 5,568,806; 5,586,553, which are also incorporated by reference herein.

Some patients are reluctant or hesitant to pierce their own skin with a medical needle, and thus encounter difficulties in correct needle placement for  
10 proper administration of the medication. Such difficulties can be attributable to insufficient manual dexterity or skill to achieve proper needle placement or, alternately to, anxiety associated with anticipated discomfort as the needle pierces the skin. This problem can be especially significant with medications delivered via a subcutaneous flexible insertion set, since incorrect placement can cause  
15 kinking of the cannula and resultant obstruction of medication flow to the patient. Cannula kinking can be due to insertion set placement at an incorrect angle relative to the patient's skin, and/or needle placement with an incorrect force and speed of insertion.

The present invention relates to an automatic injector, particularly for use  
20 with a subcutaneous insertion set, for quickly and easily placing an insertion needle through the skin of a patient at the correct insertion angle, and with a speed and force of insertion which minimizes patient discomfort.

#### SUMMARY OF THE DISCLOSURE

25 It is an object of an embodiment of the present invention to provide an improved insertion device and insertion set, which obviates for practical purposes, the above mentioned limitations.

According to an embodiment of the invention, an injector is provided for quick and easy transcutaneous placement of a medical needle through the skin of  
30 a patient, particularly such as an insertion of a subcutaneous insertion set. The injector is designed to place the needle through the skin at a selected insertion angle and with a controlled force and speed of insertion, to ensure proper needle

placement with minimal patient discomfort. The injector is particularly designed to meet these objectives, while safeguarding against undesired projection of the medical needle through free space, in the event that the injector is actuated in spaced relation to the patient's skin.

The injector comprises a spring-loaded plunger having a head for receiving and supporting an insertion set in a position with an insertion projecting outwardly for transcutaneous placement through the skin of a patient. The plunger is designed for retraction and retention within a barrel to a cocked position with a drive spring compressed in a manner applying a predetermined spring force to the plunger head. A front or nose end of the injector barrel is designed for pressed placement against the skin of a patient, at a selected needle insertion site, and in an orientation with the needle disposed at a correct or desired insertion angle. A trigger member is operable to release the plunger and thereby permit the drive spring to carry the insertion set toward the patient's skin with a controlled force and speed, resulting in proper transcutaneous placement of the insertion needle with minimal patient discomfort.

The plunger head includes a safety lock mechanism to retain the insertion set against projection from the injector barrel. In one preferred form, the safety lock mechanism comprises at least one and preferably a pair of safety lock arms for engaging and retaining the insertion set when the plunger is retracted from a fully advanced position. Each safety lock arm includes a cam lobe for engaging an appropriately shaped recess on the insertion set to prevent release thereof from the plunger head, unless and until the plunger head is returned to the fully advanced position. In such fully advanced position, the shape of the cam lobe permits quick and easy separation of the injector from the insertion set with a minimal separation force.

In operation, the safety lock arms thus prevent projection of the insertion set from the injector, in the event that the trigger member is actuated with the nose end of the barrel spaced from the skin of a patient. In that event, the plunger head is advanced with the controlled force and speed to the fully advanced position, but the insertion set is not thrown from the injector as a projectile.

Instead, the insertion set travels rapidly with the plunger head to the fully advanced position, whereat the injector can be separated with minimal separation force from the insertion set.

- 5           In an alternative preferred form, the safety lock mechanism comprises a plunger head having a cylindrical shape defining a forwardly open cavity for receiving and supporting an insertion set with the insertion needle and cannula projecting outwardly. In this embodiment, the plunger head includes a radially inwardly projecting rim at a forward or nose end thereof, wherein the rim defines
- 10 an oval-shaped opening. The size of the rim opening permits relatively free reception of a hub on the insertion set, with the infusion set oriented at an angle relative to a central axis of the plunger head and barrel. The insertion set is then reoriented to align the insertion needle coaxially with the central axis of the barrel and plunger head, so that the rim is received into a recess on the insertion set and
- 15 functions to retain the infusion set against undesired release from the injector during spring-driven placement of the needle. After needle placement, the injector is released from the insertion set with minimal separation force by orienting the injector angularly relative to the insertion set to permit free slide out passage of the hub through the oval rim opening.
- 20           In a further alternative form of the invention, the plunger head is shaped to define a laterally open undercut slot sized for relatively free slide-fit reception of the needle hub of the insertion set. In this version, the insertion set is assembled quickly and easily with the plunger head of the injector by laterally sliding the hub into the laterally open slot, thereby orienting the medical needle generally
- 25 coaxially relative to the central axis of the injector barrel and plunger head. In this position, the plunger head can be retracted and locked, followed by appropriate trigger member release for transcutaneously placing the medical insertion needle. After the needle is placed on the patient, the injector can be disassembled from the insertion set by laterally sliding the injector relative to the
- 30 needle hub. Alternatively, the injector can be withdrawn or retracted from the patient's skin to slidably separate the needle from the insertion set which remains in place on the patient's skin.

In other embodiments of the present invention, an insertion device for inserting at least a portion of at least one piercing member of an insertion set through the skin of a patient includes a device housing, a carrier body and a driver. The carrier body is slidably received within the device housing for movement between an advanced position and a retracted position. The carrier body also includes a receiving structure to support the insertion set in a position with the at least one piercing member oriented for insertion through the skin of the patient at a predetermined angle relative to the skin of the patient upon movement of the carrier body from the retracted position to the advanced position. The driver is operatively coupled between the device housing and the carrier body to urge the carrier body with a controlled force and speed from the retracted position toward the advanced position to place at least a portion of the at least one piercing member of the insertion set thorough the skin of the patient to install the insertion set to the patient. The receiving structure of the carrier body is removable from the insertion set while maintaining the installation of the insertion set to the patient.

In particular embodiments, the predetermined angle relative to the skin is about 90 degrees, between 90 degrees and 10 degrees, or is after insertion between 0 and 10 degrees. In additional embodiments, the insertion set is a transcutaneous insertion set, a subcutaneous insertion set, an infusion set, sensor set or the like. In still other embodiments, the insertion set rests mainly on the surface of the skin after insertion or the insertion set is implanted in the skin of the patient. In preferred embodiments, the at least one piercing member is a needle. In alternative embodiments, the at least one piercing member is a plurality of needles, and can also be a plurality of micro-needles. Also, in some embodiments, the insertion set insertion set can be both an infusion set and a sensor set combined into an integral unit.

In yet other embodiments the insertion device, the device housing has a forward end defining a generally planar angled insertion contact surface for placement against the skin of a patient with the device housing in a predetermined orientation relative to the patient's skin that mirrors the predetermined angle

relative to the skin of the patient. Other embodiments include a trigger mechanism that actuates the driver. For instance, the trigger mechanism includes at least one trigger for fingertip depression to actuate the driver for movement of the carrier body from the retracted position to the advanced position. In addition, the driver can include at least one spring for spring-loaded movement of the carrier body from the retracted position to the advanced position. Further, the driver can include a force changing mechanism that permits alteration of the controlled force and speed of the carrier body moving from the retracted position to the advanced position from one insertion cycle to another insertion cycle. In still further embodiments, the device housing and the carrier body include a cooperatively engageable track mechanism for guiding movement of the carrier body between the advanced and retracted positions while retaining the carrier body against rotation relative to the device housing.

In additional embodiments of the insertion device, the at least one piercing member is provided with a piercing member hub as part of the insertion set. In addition, the receiving structure of the carrier body includes a recess formed therein for mated slide-fit reception of the piercing member hub of the insertion set. Further, the recess of the receiving structure can include a laterally open undercut recess. Alternatively, the receiving structure may include a safety retainer structure that retains the at least one piercing member on the receiving structure during movement from the retracted position to the advanced position. This safety retainer structure permits separation of the at least one piercing member from the carrier body when the carrier body is in the advanced position.

Yet another embodiment of the present invention is directed to an insertion set for insertion through the skin of a patient by an insertion device. The insertion device has a slidable carrier body for movement between an advanced position and a retracted position. The carrier body of the insertion device including a receiving structure to support the insertion set in a position for insertion through the skin of the patient upon movement of the carrier body from the retracted position to the advanced position. The insertion device also having a driver operatively coupled to the carrier body that urges the carrier body with a

controlled force and speed from the retracted position toward the advanced position for insertion of the insertion set thorough the skin of the patient. The insertion set includes at least one piercing member and a set housing. The at least  
5 one piercing member includes a portion of the at least one piercing member that is insertable through the skin of the patient. The set housing is coupled to the at least one piercing member. Also, the set housing is shaped to fit within the carrier body of the insertion device to orient the at least one piercing member for placement through the skin of the patient of at least a portion of the at least one  
10 piercing member at a predetermined angle relative to the skin of the patient to install the insertion set to the patient. The set housing of the insertion set is removable from the receiving structure of the carrier body while maintaining the installation of the insertion set to the patient.

In particular embodiments of the insertion set, the predetermined angle  
15 relative to the skin is about 90 degrees, between 90 degrees and 10 degrees, or is after insertion between 0 and 10 degrees. In additional embodiments, the insertion set is a transcutaneous insertion set, a subcutaneous insertion set, an infusion set, sensor set or the like. In still other embodiments, the insertion set rests mainly on the surface of the skin after insertion or the insertion set is  
20 implanted in the skin of the patient. In preferred embodiments, the at least one piercing member is a needle. In alternative embodiments, the at least one piercing member is a plurality of needles, and can also be a plurality of micro-needles. Also, in some embodiments, the insertion set can be both an infusion set and a sensor set combined into an integral unit.

25 In other embodiments of the present invention, an insertion device for inserting at least a portion of at least one piercing member of an insertion set through the skin of a patient includes a device housing with an angled end, a carrier body and a driver. The device housing includes an angled end of the housing device to support a selectable insertion angle of the insertion device  
30 relative to the skin of the patient. The carrier body is slidably received within the device housing for movement between an advanced position and a retracted position. The carrier body also includes a receiving structure to support the



insertion set in a position with at least one piercing member oriented for insertion through the skin of the patient at the selectable insertion angle relative to the skin of the patient upon movement of the carrier body from the retracted position to the advanced position. The driver is operatively coupled between the device housing and the carrier body to urge the carrier body from the retracted position toward the advanced position to place at least a portion of the at least one piercing member of the insertion set through the skin of the patient to install the insertion set to the patient. The receiving structure of the carrier body is removable from the insertion set while maintaining the installation of the insertion set to the patient.

In particular embodiments, a portion of the angled end includes a multi-planar surface to facilitate the selection of selectable insertion angle. In additional embodiments, the angled end is a separate-rotatable member connected to the device housing by at least one pin to facilitate the movement of the device housing about the separate-rotatable member and support the selectable insertion angle of the insertion device. In other embodiments, the separate-rotatable member of the device housing includes a contact surface to provide a substantially flat contact surface for the insertion device against the patient's skin.

In additional embodiments, the piercing-member insertion angle is from 20 degrees to 45 degrees, or is between 0 and 20. In other embodiments, a portion of the angled end forms a curved opening with two arms surrounding the receiving structure, and the two arms extend beyond the receiving structure of the carrier body to support the device housing at the selectable insertion angle of the insertion device. In other embodiments, the receiving structure has a skin contacting surface with a multi-planar front end. The multi-planar front end of the receiving structure is shaped to be co-extensive with the angled end of the device housing when the carrier body is in the advanced position to facilitate insertion at the selectable insertion angle of the device housing relative to the patient's skin.

In yet other embodiments, the receiving structure may include a locking mechanism to engage at least a portion of the insertion set. In addition, the

locking mechanism may include teeth which are coupled to the insertion set and secured in position by a spring member to facilitate locking and placement of the piercing member at the selectable insertion angle of the device housing relative to the patient's skin.

In yet still other embodiments, the selectable insertion angle relative to the skin is about 90 degrees, between 90 degrees and 10 degrees, or after insertion is greater than 0 and less than or equal to 10 degrees. In additional embodiments, the insertion set is a transcutaneous insertion set, a subcutaneous insertion set, rests mainly on the surface of the skin after insertion, or is fully implanted in the skin of the patient. In preferred embodiments, the at least one piercing member is a needle. In alternative embodiments, the at least one piercing member is at least one needle or a micro-needle. In some embodiments, the insertion set is an infusion set or a sensor set. In other embodiments, the insertion device includes a trigger mechanism that actuates the driver.

Another embodiment of the present invention is for an insertion device for inserting at least a portion of at least one piercing member of an insertion set through the skin of a patient includes a device housing, a carrier body, a locking mechanism and a driver. The device housing supports the insertion device relative to the skin of the patient. The carrier body is slidably received within the device housing for movement between an advanced position and a retracted position. The carrier body includes a receiving structure to support the insertion set in a position with at least one piercing member oriented for insertion through the skin of the patient upon movement of the carrier body from the retracted position to the advanced position. The locking mechanism is included to engage at least a portion of an insertion set and secure it to the receiving structure of the carrier body, and to substantially prevent the premature release of the carrier body before securing it in position against the patient's skin. The driver is operatively coupled between the device housing and the carrier body to urge the carrier body from the retracted position toward the advanced position to place at least a portion of the at least one piercing member of the insertion set through the skin of the patient to install the insertion set to the patient. Also, the receiving structure

of the carrier body is removable from the insertion set while maintaining the installation of the insertion set to the patient. In particular embodiments, the locking mechanism includes a lever arm coupled with teeth to secure the insertion set to the receiving end of the carrier body and a spring coupled between the lever arm and the receiving end of the carrier body to bias the lever arm in a locking position and facilitate the placement of the piercing member in the patient's skin.

In further embodiments of the present invention an insertion device for inserting at least a portion of at least one piercing member of an insertion set through the skin of a patient includes a device housing, a carrier body, and a driver. The device housing supports the insertion device relative to the skin of the patient. The carrier body is slidably received within the device housing for movement between an advanced position and a retracted position. The carrier body also includes a receiving structure to support the insertion set in a position with at least one piercing member oriented for insertion through the skin of the patient upon movement of the carrier body from the retracted position to the advanced position. The driver is operatively coupled between the device housing and the carrier body to move the carrier body from the retracted position toward the advanced position to place at least a portion of the at least one piercing member of the insertion set through the skin of the patient to install the insertion set to the patient. Further, the receiving structure of the carrier body is removable from the insertion set while maintaining the installation of the insertion set to the patient.

In particular embodiments, the carrier body is a plunger to hold the insertion set and to insert it in the patient's skin by moving from the retracted position to the advanced position. Also in other embodiments, the carrier body is operatively coupled to a detent within the device housing. The detent has a threshold force level that must be overcome to permit and to facilitate the movement of the plunger from the retracted position to the advanced position with a controlled force and speed. In additional embodiments, the distance traveled by the plunger within the device housing is equal to at least a distance required to fully insert the insertion set in the patient's skin that is at least equal to

an implantable length of the piercing member. Additionally, the carrier body may be adapted for use with different types of insertion sets.

Other features and advantages of the invention will become apparent from  
5 the following detailed description, taken in conjunction with the accompanying drawings which illustrate, by way of example, various features of embodiments of the invention.

#### BRIEF DESCRIPTION OF THE DRAWINGS

10 A detailed description of embodiments of the invention will be made with reference to the accompanying drawings, wherein like numerals designate corresponding parts in the several figures.

Fig. 1 is a perspective view illustrating use of an automatic injector embodying the novel features of the invention.

15 Fig. 2 is an enlarged front elevation view of the injector shown in Fig. 1.

Fig. 3 is a front or nose end view of the injector, taken generally on the line 3-3 of Fig. 2.

Fig. 4 is an enlarged exploded perspective view illustrating assembly of the injector with a subcutaneous insertion set.

20 Fig. 5 is a further enlarged longitudinal sectional view taken generally on the line 5-5 of Fig. 4.

Fig. 6 is a transverse sectional view taken generally on the line 6-6 of Fig. 5.

25 Fig. 7 is an enlarged longitudinal sectional view taken generally on the line 7-7 of Fig. 2.

Fig. 8 is an enlarged and exploded fragmented perspective view illustrating a trigger assembly for use in the injector.

30 Fig. 9 is a longitudinal sectional view similar to Fig. 5, and showing the injector with insertion set received therein for transcutaneous placement through the skin of a patient.

Fig. 10 is a transverse sectional view taken generally on the line 10-10 of Fig. 9.

Fig. 11 is a longitudinal sectional view taken generally on the line 11-11 of Fig. 9.

Fig. 12 is a rear end elevation view taken generally on the line 12-12 of Fig. 11, and depicting the trigger assembly in a locked position;

Fig. 13 is an enlarged fragmented longitudinal view similar to a portion of Fig. 11, but depicting actuation of the trigger assembly for releasing the spring-loaded plunger.

Fig. 14 is a rear end elevation view taken generally on the line 14-14 of Fig. 13, similar to Fig. 12, but showing the trigger assembly in an unlocked position.

Fig. 15 is a fragmented longitudinal sectional view depicting the spring-loaded plunger in a fully advanced position with the infusion set placed on the patient's skin.

Fig. 16 is an exploded perspective view illustrating separation of the insertion needle from the cannula of the subcutaneous insertion set.

Fig. 17 is a perspective view depicting an alternative preferred form of the invention.

Fig. 18 is a front elevation view of the injector shown in Fig. 17.

Fig. 19 is a front or nose end view of the injector, taken generally on the line 19-19 of Fig. 18.

Fig. 20 is an enlarged side elevation view of the injector, taken generally on the line 20-20 of Fig. 19.

Fig. 21 is a further enlarged longitudinal sectional view taken generally on the line 21-21 of Fig. 17.

Fig. 22 is an enlarged exploded perspective view illustrating construction details of a plunger and trigger member for use in the injector of Fig. 17.

Fig. 23 is an enlarged longitudinal sectional view similar to Fig. 21, and depicting the injector with the trigger member in a cocked position.

Fig. 24 is a fragmented perspective view showing the upper end of the injector depicted in Fig. 23, with the trigger member in the cocked position.

Fig. 25 is an enlarged and fragmented longitudinal sectional view illustrating actuation of the trigger member.

Fig. 26 is an enlarged and fragmented longitudinal sectional view showing  
5 the plunger in a fully advanced position with the infusion set placed on the patient's skin.

Fig. 27 is an enlarged fragmented longitudinal sectional view taken generally on the line 27-27 of Fig. 22, and depicting a portion of the plunger.

Fig. 28 is a front or nose end elevational view of the plunger, taken  
10 generally on the line 28-28 of Fig. 27.

Fig. 29 is an enlarged fragmented longitudinal sectional view illustrating release of the injector from an infusion set placed on the patient's skin.

Fig. 30 is an exploded prospective view generally similar to Fig. 17, but depicting a further alternative preferred form of the invention, and showing  
15 assembly of an insertion set with the illustrative injector.

Fig. 31 is a perspective view similar to Fig. 32, depicting further assembly of the insertion set with the injector.

Fig. 32 is an enlarged fragmented vertical sectional view taken generally on the line 32-32 of Fig. 31.

Fig. 33 is a perspective view showing use of the injector of Figs. 30-32 for  
20 transcutaneous placement of the insertion set.

Fig. 34 is an exploded perspective view similar to Fig. 33, and showing use of the injector to separate a medical needle from the installed insertion set.

Fig. 35 is a perspective view of an insertion device with one type of an  
25 insertion set in accordance with a second embodiment of the present invention.

Fig. 36 is a bottom perspective view of the insertion device of Fig. 35.

Fig. 37 is a side plan view of the insertion device and insertion set shown in Fig. 35.

Fig. 38 is an exploded cross-sectional view of the insertion device and the  
30 one type of insertion set as shown along the line 38-38 in Fig. 37.

Fig. 39 is a top perspective view of one type of insertion set for use with the insertion device shown in Fig. 35.

Figs. 40a-40g illustrate the steps of inserting the one type of insertion set of Fig. 39 with the insertion device of Fig. 35.

Fig. 41 is a perspective view of an insertion device with one type of an  
5 insertion set in accordance with a third embodiment of the present invention.

Fig. 42 is an exploded perspective view of the insertion device shown in Fig. 41.

Fig. 43 is an exploded side plan view of the insertion device and the one type of insertion set shown in Fig. 41.

10 Fig. 44 is an enlarged side plan view of the one type of insertion set held in a carrier body of the insertion device shown in Fig. 41.

Fig. 45 is a front perspective view of the insertion device and the one type of insertion set shown in Fig. 41.

15 Fig. 46 is a cross-sectional view of the insertion device and the one type of insertion set as shown along the line 46-46 in Fig. 45.

Fig. 47 is a top schematic view of an insertion device in accordance with a fourth embodiment of the present invention.

Figs. 48a-48d are cross-sectional views of a force changing mechanism for use with embodiments of the present invention.

20 Fig. 49 is a perspective view of an insertion device in accordance with a fifth embodiment of the present invention.

Fig. 50 is an exploded view of the embodiment shown in Fig. 49.

Figs. 51 (a)-(e) show the use of the insertion device with an insertion set in accordance with the embodiment shown in Fig. 49.

25 Figs. 52 (a)-(f) show various insertion angles obtainable with the insertion device in accordance with the embodiment shown in Fig. 49.

Figs. 53 (a)-(d) show the use of a locking mechanism of the insertion device used with the embodiment of the present invention shown in Figs. 49-53(d).

30 Fig. 54 is a perspective view of a separate rotatable end for an insertion device in accordance with a sixth embodiment of the present invention.

Fig. 55 is a side plan view of the rotatable end embodiment shown in Fig. 54.

Fig. 56 is a front top plan view of the rotatable end embodiment shown in Fig. 54.

Fig. 57 is a perspective view of the rotatable end embodiment shown in Fig. 54.

Figs. 58 (a)-(f) show various insertion angles obtainable with the insertion device using the rotatable end in accordance with the embodiment shown in Fig.

5 54.

Fig. 59 is a cross-sectional view of an insertion device in accordance with a seventh embodiment of the present invention.

Fig. 60 is a cross-sectional view of an insertion device in accordance with an eighth embodiment of the present invention.

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#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

As shown in the drawings for purposes of illustration, the invention is embodied in an insertion device for insertion sets such as an infusion set, sensor set, medical device, or the like. Further embodiments of the insertion device may be used to insert other insertion sets or medical devices such as biodegradable implants, capsules, impregnated threads (with medications or the like). Other insertion sets may be directed to a threaded needle insertion set, such as that described in U.S. Patent No. 5,584,813 issued December 17, 1996 to Livingston et al. entitled "Subcutaneous Injection Set" and U.S. Patent No. 5,779,665 issued on July 14, 1998 to Mastrototaro et al. entitled "Transdermal Introducer Assembly", which are herein incorporated by reference. In addition, the insertion sets may be coated with medications, or other agents, that inhibit infection and/or promote healing of the insertion site. Preferred embodiments of the insertion device and insertion sets are for transcutaneous placement of the insertion set in subcutaneous tissue. However, in alternative embodiments, the insertion set may be inserted into other subdermal tissues. In addition, still further embodiments may be used to place the sets in other types tissue, such as muscle, lymph, organ tissue or the like, and used in animal tissue. In preferred embodiments of the present invention, the insertion device is loaded with a standard hand-held insertion set, or the like, and then placed against the skin of the user, where the insertion device is activated to transcutaneously place a portion of the insertion set, or the like, subcutaneously in a quick manner that minimizes pain and/or

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discomfort to the user. However, it will be recognized that further embodiments of the invention may be used to place an entire insertion set, or the like, beneath the skin, rather than just a portion of the insertion set. As discussed, preferred  
5   embodiments of the insertion device are designed to accommodate off-the-shelf insertion sets, or the like. But, alternative embodiments may be used with customized insertion sets, or the like that have been altered to fit the insertion device in a particular orientation or configuration to improve safety and/or assure proper placement of the insertion set, or the like. In still other embodiments, the  
10   insertion sets, or the like may be angled and the devices are capable of insertion at angles between 0 and 90 degrees relative to the skin surface after insertion of the insertion set.

In preferred embodiments, the insertion set includes at least one piercing member to pierce the skin during insertion. In particular embodiments, the  
15   piercing member is a metal needle. In alternative embodiments, the needle may be hollow, solid, half needle (or other fraction), or the like. In further alternative embodiments, the piercing member may be made out of other materials, such as ceramic, plastic, composites, silicon micro-needles, biodegradable, hydrophilic substances, substances that soften and/or change once in contact with the body  
20   and/or bodily fluids, or the like. In other alternative embodiments, the insertion set may include more than one piercing member. For example, a single insertion set may include a piercing member for an infusion portion and another piercing member for a separate sensor portion, or the like. Alternatively, the insertion set may include a plurality of small piercing members on a small patch or substrate,  
25   such as a series of hollow micro-needles (such as from silicon, plastics, metal or the like) for infusion of a medication or a series of solid micro-needles for sensor applications (such as from silicon, plastics, metal or the like), which micro-needles are used to penetrate the skin.

As shown in the exemplary drawings, an injector (or insertion device) in  
30   accordance with a first embodiment of the present invention is referred to generally by the reference numeral 10 is provided for quick and easy transcutaneous placement of a medical needle, particularly such as an insertion

needle 12 of the type provided with a subcutaneous insertion set 14 as depicted in Figs. 4 and 7. The injector 10 includes a trigger-type actuator mechanism for transcutaneous placement of the insertion needle 12 with a controlled speed and force, and with the insertion needle 12 oriented at a desired angular position relative to the skin 16 (Figs. 1 and 9) of the patient.

The automatic injector 10 of the present invention, as shown in the illustrative drawings, is particularly designed for placement of the insertion needle 12 of a subcutaneous insertion set 14, such as an insertion set of the general type shown and described in U.S. Patents 4,755,173; 5,176,662; and 5,257,980, which are incorporated by reference herein. Such insertion sets 14 are used to infuse medical fluids such as selected medications to a patient, with one example being the administration of insulin to a diabetic by operation of a programmable medication infusion pump (not shown) of the type described in U.S. Patent 4,685,903. Alternatively, the injector 10 may be used to transcutaneously place a medical needle associated with other types of insertion sets, such as transcutaneous sensor insertion sets of the general type shown and described in U.S. Patents 5,390,671; 5,560,806 and 5,586,553, which are also incorporated by reference herein. Such insertion sets are used, for example, to monitoring patient glucose levels.

As shown best in Fig. 4 with respect to an insertion set 14 for infusing medical fluids to a patient, the insertion needle 12 is connected to a hub 18 at a rear or proximal end thereof, and protrudes through a housing 20 of the insertion set 14, wherein the housing 20 defines an internal chamber (not shown) for receiving medication via infusion tubing 22. An enlarged base, typically in the form of resilient or flexible wings 24, is provided on the housing 20 for stable affixation to the skin 16 of a patient. The insertion needle 12 protrudes downwardly through the housing 20 and the winged base 24 to extend through a soft and flexible cannula 26. The insertion needle 12 is provided for transcutaneous placement of the cannula 26, after which the insertion needle is retracted from the set 14 (Fig. 16) to permit medication delivery through the cannula 26 to the patient.

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The injector 10 of the present invention represents a simple device which can be used by the patient to quickly and easily place the subcutaneous insertion set 14 in a proper transcutaneous position and orientation, at a selected medication insertion site. The injector 10 is designed to project the insertion set toward the patient's skin 16 at a controlled force and speed for quickly piercing the skin in a manner insuring proper placement of the insertion needle 12 and cannula 26, while minimizing patient anxiety and/or discomfort. Improper and/or partial placement of the insertion needle 12 is thus avoided.

10 In general terms, as shown in one preferred form in Figs. 1-5, the injector 10 comprises a cylindrical forward barrel 28 (or device housing) having a plunger 30 (or carrier body) mounted therein for longitudinal sliding movement within a hollow bore between a forward advanced position (Fig. 5) and a rearward retracted position (Fig. 9). The plunger 30 has a head 32 at a forward end thereof for releasably receiving and retaining the subcutaneous insertion set 14, in a manner to be described in more detail. A rear end of the plunger 30 cooperates with a trigger-type actuator assembly 34 mounted on the rear end of the barrel 28. The trigger actuator assembly 34 (or driver) is adapted to hold the plunger 30 in a retracted position, against the force of a compressed drive spring 36. A trigger button 38 of the actuator assembly 34 is adapted for fingertip depression to release the plunger 30 for spring-loaded travel toward the advanced position, and corresponding transcutaneous placement of the insertion needle 12 through the patient's skin.

25 Figs. 2-5 illustrate construction details of the injector barrel 28, wherein the forward or nose end thereof defines a flat and generally planar surface for placement against the skin of a patient (Fig. 1) with a longitudinal axis of the barrel 28 oriented generally perpendicular to the patient's skin 16. The barrel 28 has a size and shape for substantially mated sliding fit reception of the infusion set 14, with the insertion needle 12 and related cannula 26 projecting in a direction for placement on a patient. In this regard, the nose end of the barrel 28 defines an opposed pair of relatively wide and open-ended cut outs 40 for slide-fit reception of the oppositely projecting base wings 24. A narrower slot 42 is also

formed in the barrel nose end, at a location for slide-fit reception of the infusion tubing 22 attached to the infusion set 14. Thus, the forward or nose end of the barrel 28 accommodates sliding reception of the subcutaneous insertion set 14 therein for movement along the cut outs 40 and the slot 42 between the advanced position (Fig. 5) disposed substantially at the forwardmost end of the barrel 28, and the retracted position (Fig. 9) with the base wings 24 and infusion tubing 22 positioned substantially at the inboard ends of the cut outs 40 and the associated slot 42.

10       The plunger 30 includes the head 32 of generally cylindrical shape for slide-fit reception within the injector barrel 28. A forward end of the head 32 includes a cylindrical counterbore recess 44 for receiving the hub 18 and housing 20 of the insertion set 14, with the enlarged base wings 24 fitted against a pair of outwardly protruding backstop flanges 46 adapted for slide-fit reception within the cut outs 40 in the barrel nose end. A pair of track arms 48 (Fig. 5) protrude rearwardly from the plunger head 32 and include out-turned latch fingers 50 for guided reception within longitudinally extending track slots 52 formed in the barrel 28 at a location spaced aft from the barrel nose end. These track arms 48 thus cooperate with the barrel track slots 52 to guide the plunger 30 between the advanced position (Figs. 5 and 7) and the retracted position (Fig. 9).

20       The plunger 30 also includes a central drive stem 54 (Fig. 5) which protrudes rearwardly from the plunger head 32 within the barrel interior. The rearward end of the drive stem 54 is longitudinally split to define a pair of trigger arms 56 which have out-turned trigger fingers 58 on the rearward ends thereof.

25       The trigger-type actuator assembly 34 is mounted on the rearward end of the injector barrel 28, and generally functions to releasibly retain the plunger 30 in a retracted and cocked position, ready for rapid and spring-loaded actuation upon depression of the trigger button 38 to place the insertion set 14 on the patient. More particularly, as shown best in Figs. 5-9, the trigger assembly 34 comprises a main support cap 60 having a mounting sleeve 62 protruding in a press-fit and preferably adhesively connected manner into the rear or aft end of the injector barrel 28. The drive spring 36 comprises a coil spring positioned

about the drive stem 54 on the plunger 30 and reacts between a rearward face 64 of the plunger head 32, and a shoulder 66 on the support cap 60. The drive spring 36 normally biases the plunger 30 toward the advanced position (Figs. 5 and 7).

- 5 However, an insertion set 14 seated in the plunger head 32 can be pressed rearwardly against the plunger 30 to move the plunger to the retracted position, as viewed in Fig. 9, with the trigger fingers 58 passed through a conical or tapered latch bore 68 formed in the support cap 60 to engaging a shoulder 70 on an opposite side of the support cap 60. In this regard, the trigger fingers 58 have
- 10 ramped outboard faces to accommodate movement of the fingers 58 radially toward each other as they pass through the latch bore 68. When the trigger fingers 58 pass entirely through the bore 68, the spring resilience of the trigger arms 56 is sufficient to spread the trigger fingers 58 so that they engage the shoulder 70. In this retracted plunger position, the drive spring 36 is retained in a
- 15 compressed and cocked condition, with the insertion set 14 including the insertion needle 12 and related cannula 26 withdrawn into the interior of the barrel 28, in spaced relation to the patient's skin 16.

- The trigger actuator assembly 34 additionally includes an actuator pin 72 mounted within a noncircular bore 74 (Figs. 6 and 7) formed in the support cap
- 20 60 for longitudinal sliding movement through a short stroke, relative to the plunger 30. In this regard, the actuator pin 72 includes one or more noncircular lands 76 for slide-fit reception within the bore 74, to prevent actuator pin rotation therein. The actuator pin 72 is held within the bore 74 by a stepped lock ring 78 which is retained against a rearward end of the support cap 60 by a press-fit outer
- 25 retainer sleeve 80 having an inturned rim 82 at the rearward end thereof. Importantly, as shown best in Fig. 8, an oblong land 84 is formed on the actuator pin 72 for mated slide-fit reception through an oblong recess 85 formed in the lock ring 78. A return spring 86 (Fig. 7) is carried within the support cap bore 74 and reacts between the shoulder 70 and a nose end of the actuator pin 80 for
- 30 biasing the actuator pin 80 rearwardly within the support cap.

The rearmost end of the actuator pin 72 defines the trigger button 38. As shown in Figs. 11 and 13, the trigger button 38 can be depressed with a fingertip

to move the actuator pin 72 through a short stroke against the return spring 86 in a direction toward the trigger fingers 58 at the rear end of the plunger 30. As shown best in Fig. 13, the actuator pin 72 has a hollowed cylindrical forward tip 88 with a diametric size for engaging and squeezing the trigger fingers 58 together at the rear end of the plunger 30, in a manner enabling those trigger fingers 58 to pass back through the tapered conical latch bore 68. As soon as the trigger fingers 58 thus release from engagement with the shoulder 70 on the support cap 60, the drive spring 36 translates the plunger 30 with the insertion set 14 thereon with a rapid and controlled force and speed toward the advanced position, resulting in transcutaneous placement of the needle 12 and cannula 26, as viewed in Fig. 15. Importantly, the spring rate characteristics of the drive spring 36 and the distance of plunger stroke are chosen for a substantially optimized and proper transcutaneous placement of the needle 12 and cannula 26, all in a manner which minimizes patient discomfort during the needle placement procedure. Moreover, by forming the nose end of the injector barrel 28 with a squared-off shape as shown, the injector 10 can be easily oriented substantially perpendicular to the skin 16 for proper placement of the insertion set.

Depression of the actuator pin 72 by means of the trigger button 38 requires the lock ring 78 to be rotatably oriented in a position aligning the oblong recess 85 therein with the oblong land 84 on the actuator pin. Accordingly, when these oblong structures are rotationally aligned (Figs. 13-14), the injector 10 is armed for trigger button depression and corresponding release of the retracted and cocked plunger. However, the lock ring 78 can be rotated relative to the actuator pin 72 to misalign these oblong structures, as shown in Figs. 9-12, whereupon the actuator pin 72 is locked in a rearward position against depression and actuation. A set pin 90 on the lock ring 78 may be provided and received within an accurate notch 92 formed in the retainer sleeve flange rim 82, to permit lock ring rotation back-and-forth through a part circle increment, on the order of about 90 degrees. Appropriate indicia may be applied to the retainer sleeve rim 82, such as the letter "L" for "locked" and the letter "A" for "armed", as viewed in Figs. 12 and 14, to provide a visual indication of the setting of the trigger assembly 34.

In accordance with one aspect of the invention, the plunger head 32 additionally includes a safety lock mechanism in the form of a pair of safety lock arms 94 pivotally carried in narrow slots 96 formed in the plunger head 32.

- 5 These safety lock arms 94 have rearward ends connected to the head 30 by pivot pins 98, and forward ends defining contoured lock fingers 100 which protrude into the plunger head recess 44. As shown in Fig. 7, the safety lock arms 94 and their associated lock fingers 100 have a size and shape so that the fingers 100 can engage and retain the hub 18 of the insertion set 14, for example, by fitting into a  
10 recess 101 defined between the hub 18 and housing 20 of the insertion set. Importantly, the locations of the lock arm pivot points are chosen to insure that the lock arms 94 engage and retain the insertion set 14 whenever the plunger 30 is moved from the advanced position (Fig. 7) toward and to the retracted position (Fig. 9). When the plunger 30 reaches the fully advanced position, the safety lock  
15 arms 94 including their respective pivot pins 98 are disposed within the wide cut outs 40 and are therefore free to swing outwardly, relative to the insertion set 14, to accommodate separation of the insertion set from the injector 10 with a substantially minimum separation force. This configuration has been found to be highly effective as a safeguard to prevent the insertion set 14 from being thrown  
20 as a projectile from the injector 10, in the event that the trigger assembly 34 is activated without prior placement of the injector 10 firmly against the patient's skin 16.

- In use, the subcutaneous insertion set 14 can be placed quickly and easily into the open nose end of the injector barrel 28, within the recess 44 formed in the plunger  
25 head 32. Such assembly of the insertion set 14 with the injector 10 requires simple alignment of the base wings 24 and infusion tubing 22 with the appropriate cut outs and slots 40, 42 formed in the nose end of the barrel 28. The insertion set 14 and plunger 30 can then be manually retracted rearwardly, against the drive spring 36, to the retracted position with the plunger 30 cocked and  
30 latched as viewed in Figs. 9 and 11. The injector 10 can then be placed firmly against the patient's skin 16, with the insertion set 14 supported in the proper orientation and at a predetermined distance from the skin 16. Simple depression

of the trigger button 38 releases the cocked plunger 30 for spring-loaded travel rapidly albeit with a controlled speed and force of insertion, to ensure penetration of the patient's skin with minimal discomfort, and in a manner which properly  
5 places the insertion needle and cannula. The safety lock arms 94 prevent accidental projection of the insertion set 14 through free space, in the event that the trigger button 38 is prematurely depressed. When the insertion set 14 is properly placed, however, the safety lock arms 94 release from the insertion set with minimal force, for easy separation of the injector 10 from the insertion set  
10 14.

In preferred embodiments, the controlled speed and force of the insertion device is obtained by selecting a spring constant of a spring to propel and insert the insertion set at the proper speed and force to ensure penetration with minimal discomfort. In alternative embodiments, as shown in Figs. 48a-48d, there is the  
15 need to vary the speed and force, from one insertion cycle to the next, to accommodate different insertion sets (such as finer needles, sensor sets fragility or the like) and insertion site conditions (such as overweight, underweight, children or the like). As shown in Fig. 48a, a force changing mechanism 1000 having a spring 1002 enclosed in a sealed compartment 1004 is used with a set  
20 (or adjustable) orifice 1006 to allow equalization of internal and ambient pressures during the insertion stroke of the insertion device. The sealed compartment 1004 includes sealing O-rings 1008 and 1010 to seal the sealed compartment 1004. The O-ring 1008 seals the insertion set carrier body 1012, and the O-ring 1010 seals the actuator housing 1014 (which contains the orifice  
25 1006) of the force generating mechanism 1000. The force changing mechanism 1000 may be activated by, for example, a trigger 1016 that is biased by a spring 1018 to close off the orifice 1006 until depressed. The limiting flow through the office 1006 acts as a dampening force, counteracting the spring force from the spring 1002, thereby allowing control of insertion speed and force. The orifice  
30 size can be adjustably attained through a number of approaches, such as bearing 1020 and spring 1022 that blocks the orifice 1006 and resists air flow based on the tension of the spring 1022 on the bearing 1020 (see Fig. 48b); while



- presenting a lower resistance during retraction as the air contained in the sealed compartment 1004 is compressed, forcing bearing 1020 against spring 1022 to unseat the bearing 1022 from the orifice 1006 to present the maximum orifice
- 5 size for escaping air during compression of spring 1002. This structure minimizes the force needed to compress spring 1022 by allowing air in the sealed compartment 1004 to escape freely and quickly through the orifice 1006; rather than be compressed within the sealed compartment 1004 because the orifice 1006 is restricted by bearing 1002. In another alternative, as shown in Fig. 48c, a disk
- 10 1024 has a plurality of various sized holes 1026(1) to 1026(n). The disk 1024 is rotatable over the orifice 1006 to sequentially obstruct, completely obstruct or partially obstruct the orifice 1006 flow path and changes the effective size of the orifice 1006 by blocking the orifice 1006 with the various sized holes 1026(1) through 1026(n). In another embodiment, as shown in Fig. 48d, a tapered valve
- 15 plug 1028 is threaded into position relative to the orifice 1006 to change the effective size of the orifice 1006. Other orifice 1006 size changing methods may be used. In addition, other methods of controlling the insertion speed and force may be used, such as controlled friction, change in spring tension, hydraulics, pneumatics or the like may be used.
- 20 Following separation of the injector 10 from the placed insertion set 14, the insertion needle 12 can be withdrawn quickly and easily from the cannula as viewed in Fig. 16. Thereafter, the insertion set 14 can be used in a normal manner to deliver a selected medication through the infusion tubing 22 and cannula 26 to the patient.
- 25 An alternative preferred form of the invention is shown in Figs. 17-29, wherein components corresponding in structure and function to those described previously with respect to Figs. 1-16 are identified by common reference numerals increased by 100. The embodiment of Figs. 17-29 show a modified injector 110 constructed from a reduced number of parts and including an
- 30 alternative safety lock mechanism for preventing undesired projection of the insertion set 14 through free space in the event of injector operation without placing the nose end thereof firmly against the skin 16 of a patient. However, the

alternative safety lock mechanism again permits quick and easy separation of the injector 110 from the insertion set 14, with minimal separation force. Once again, although an insertion set for infusing medical fluids to a patient will be shown and described, it will be understood that alternative insertion sets such as transcutaneous sensor insertion sets and the like as previously referenced herein may be used with the injector 110.

In general, the modified injector 110 comprises a plunger 130 and a trigger-type actuator 134 assembled with a generally cylindrical hollow barrel 128. The plunger 130 has a generally cylindrical plunger head 132 which defines a counterbore recess 144 for receiving and retaining the hub 18 of the infusion set 14. As shown best in Figs. 27-29, a radially inwardly projecting rim 202 is formed on the plunger head 132 generally at a leading or nose end of the recess 144, wherein this rim 202 has a noncircular and preferably oval or elliptical shape (Fig. 28) to accommodate reception of the hub 18 into the recess 144 provided that the hub 18 is oriented angularly relative to a central longitudinal axis of the plunger 130 and barrel 128. Similar angular orientation of these components accommodates quick and easy separation thereof. However, when the insertion set 14 is oriented with the medical needle 12 aligned coaxially with the barrel center axis, a portion of the rim 202 projects into the insertion set recess 101 to prevent release of the insertion set 14 from the injector 110.

More specifically, with reference to Figs. 17-20, the barrel 128 again has a forward or nose end defining a flat and generally planar surface for firm placement against the skin of a patient. The nose end of the barrel 128 has a pair of relatively wide and generally opposed cut outs 140 formed therein for slide-fit reception of the base wings 24 of the insertion set 14, in combination with a narrower slot 142 for slide-fit reception of the infusion tubing 22. This slot 142 may be formed in one or both sides of the barrel nose end.

The plunger 130 is slidably fitted into the barrel 128 for movement between an advanced position shown in Figs. 17, 18, 20 and 21, and a retracted position shown in Fig. 23. The plunger 130 includes the modified plunger head 132 of generally cylindrical shape, formed preferably to include a shallow notch

or groove 133 in one side thereof for slide-fit reception of the infusion tubing 22 on the insertion set 14. In this regard, the plunger head groove 133 is formed in a position aligned with the narrow slot 142 in the nose end of the barrel.

5           The plunger head 132 is formed integrally with a drive stem 154 which projects rearwardly within the barrel interior. As shown best in Fig. 22, the drive stem 154 is flanked by and formed integrally with a pair of rearwardly projecting track arms 148 which have latch fingers 150 formed at the rear ends thereof. As shown in Figs. 21 and 23, these latch fingers 150 are received slidably within  
10           longitudinally extending track slots 152 formed in the barrel 128, and function to guide the plunger 130 between the advanced and retracted positions. Cushioning material (not shown) may be included at the leading ends of the track slots 152 to form a combined stop upon spring driver advancing motion of the plunger 130, as will be described.

15           The plunger 130 additionally includes a pair of trigger arms 156 which project generally rearwardly from a rear end of the drive stem 154 and have out-turned trigger fingers 158 at the rear ends thereof (Fig. 22). These trigger fingers 158 are adapted and sized for partial radial compression toward each other as they ride within the barrel base when the plunger 130 is displaced from the advanced  
20           position (Fig. 21) to the retracted position (Fig. 23). As the retracted position is reached, the trigger fingers 158 are spring-loaded by the resiliency of the trigger arms 156 to move outwardly for partial reception into relatively short trigger slots 159 formed in the barrel 128. In this position, as shown in Fig. 23, the triggers fingers 158 retain the plunger 130 in the retracted position.

25           A drive spring 136 is mounted within the barrel 128 to react between the trigger-type actuator 134 and the plunger 130, in the same manner as previously described with respect to Figs. 1-16. In this regard, the trigger actuator 134 comprises a generally cylindrical actuator sleeve 188 mounted slidably within the barrel 128 at the rear or upper end thereof. This actuator sleeve 188 has a tapered  
30           or ramped leading edge face 188' (Figs. 22, 23 and 25) for engaging matingly shaped ramped outer faces of the trigger fingers 158, to radially compress the trigger arms 156 and release the plunger 130 for spring-loaded travel from the

retracted and cocked position to the advanced position. A trigger button 138 is formed integrally with the actuator sleeve 188 and is exposed for fingertip depression at the rear or top of the barrel 128 to move the actuator sleeve 188 into  
5 releasing engagement with the trigger fingers 158.

As shown best in Figs. 22 and 24-26, the triggers button 138 extends through an opening formed in the rear of the barrel 128, generally within a lock sleeve 178 formed integrally with the barrel 128. The lock sleeve 178 defines an oppositely formed pair of guide slots 192 for aligned reception of a pair of  
10 outwardly radiating lock tabs 184 formed on the trigger button 138. When the tabs 184 and rotationally aligned with the guide slots 192, the trigger button 138 can be depressed to actuate the spring-locked plunger, as described. However, the lock tabs 184 have sufficient length to permit fingertip rotation of the actuator 134 to re-position the tabs 184 within shallow lock grooves 193 formed adjacent  
15 the guide slots 192. When the tabs 184 are seated in the lock grooves 193, the lock sleeve 178 blocks depression of the triggers button 138 and thereby locks the injector 110 against actuation. Return rotation of the actuation 134 to re-align the tabs 184 with the guide slots 192 is required before the injector can be activated.

In accordance with one aspect of the invention, the plunger head 132  
20 includes the safety lock mechanism in the form of the noncircular rim 202 at the leading end of the recess 144 in the plunger head. As shown in Figs. 27 and 28, the rim 202 has a generally elliptical shape defining a major axis that is greater than the diameter of the hub 18 on the insertion set 14, and a minor axis that is less than the hub diameter. With this geometry, and by providing sufficient axial  
25 depth to the plunger head recess 144, the hub 18 can be fitted into the plunger head by angularly orienting the components to permit slide-fit of the hub 18 through the major axis portion of the rim 202. Subsequent re-orientation of the components to align the medical needle 12 generally coaxially with plunger head 32 enables the minor axis portion of the rim 202 to project into the insertion set  
30 recess 101, thereby locking the components together. Thereafter, when the insertion set 14 is placed on the patient (Fig. 29), the components are easily separated by lifting the injector 110 off the insertion set 14 at the same angle to

allow the hub 18 to press freely through the major axis center of the rim 202. Importantly, such engagement and disengagement of the components occurs with essentially no resistance force to separation. The infusion set 14 can be oriented  
5 angularly relative to the plunger 130 only when the plunger is in the advanced position, with the adjacent barrel 128 precluding such angular orientation when the plunger 130 is moved rearwardly from the restricted position.

In an alternative mode of operation, subsequent to actuation of the injector 110 to place the insertion set 14 of the patient, the injector 110 can be simply  
10 withdrawn or retracted in a direction away from the patient's skin 16, in which case the rim 202 at the nose end of the plunger head 132 will engage the needle hub 18 and thereby gently withdraw the medical needle 12 from the insertion set 14. In this manner, the needle 12 is retracted from the cannula 26 which remains at the desired transcutaneous insertion site.

A further alternative preferred form of the invention is shown in Figs. 30-34, wherein a further modified injector 210 is constructed and operated generally as shown and described in Figs. 17-29, but wherein an alternative configuration for a plunger head 232 is provided. Figs. 30-32 show the injector 210 with the  
15 plunger head 232 in the advanced position within the front or nose end of the barrel 128 which includes the wide cut outs 140 and the narrow slot 142 for respective slide-fit reception of the base wings 24 and the tubing 22 of the insertion set 14. As shown, the modified plunger head 232 has a laterally open recess 244 formed therein of undercut geometry and laterally exposed through the cut outs 140 when the plunger is in the advanced position. The insertion set 14  
20 can be slide-fit assembled with the plunger head 232, by fitting the hub 18 into the wider upper region of the recess 144, with an inturned rim 302 at the leading end of the plunger head fitting into the insertion set recess 101. A laterally open gap 303 (Fig. 34) in the rim 302 permits slide-fit reception of the hub 18 into the recess 244, and a short carrier post 304 (Fig. 32) may be provided at the base of  
25 the recess 244 to seat within a shallow detent in the top of the hub.  
30

With the insertion set 14 assembled with the plunger head 232, as viewed in Fig. 32, the plunger can be retracted and cocked as previously shown and

insertion sets 400 (as exemplary shown in Fig. 39 as an infusion set), or the like, that are inserted with the piercing member 402 (or needle) at 90 degrees (or perpendicular) to the skin surface after insertion. In preferred embodiments, the carrier body 504 is permanently coupled to the barrel 502 and new insertion sets 400 are attached to the carrier body 504 for each new insertion. However, in alternative embodiments, the carrier body 504 may be a disposable that is replaced after each insertion so that, for instance, a carrier body 504 may be shipped with a pre-installed insertion set 400 and then loaded into the barrel 502 of the insertion device 500.

The insertion device 500 features a low profile compact package that tends to minimize the effects of hand movement during insertion of the insertion set 400. In this embodiment, the release button 508 is depressed to release the insertion set 400, or the like, from the carrier body 504 of the insertion device 500; rather than engaging or disengaging the insertion set 14 using a lateral slot as shown in Figs. 31-34 above. The release button 508 can be used before or after insertion of the insertion set 400, or the like. To facilitate insertion of an insertion set 400, or the like, the insertion device 500 utilizes dual trigger buttons 510 and 512, which provide an extra margin of safety and substantially prevents accidental activation of the insertion device 500 upon contact with the skin surface. This obviates the need for a lock and unlock position on the activation buttons (or triggers) of the earlier insertion devices shown in Figs. 1-34. The insertion device 500 also includes another rim on the carrier body 504 that forms the seating flange 506 to hold a rim 404 (or wing) of the insertion set 400, or the like, that carries an adhesive 406 for adhering the insertion set 400 to the surface of the skin. Upon activation of the insertion device 500 to move the carrier body to the advanced position, the seating flange 506 presses the adhesive 406 and rim 404 of the insertion set 400 firmly against the skin surface to provide positive seating and attachment of the insertion set 400 to the skin. This may make it unnecessary to require placement of an additional adhesive patch prior to or after inserting an insertion set 400 to secure the insertion set 400 at the insertion site. The insertion device 500 further includes an automatic release of the piercing

member (or needle) hub 408 and piercing member 402 (or needle) from the insertion set 400, or the like, after the insertion set 400, or the like, has been inserted. This permits the insertion set 400 to be left on the skin surface without  
5 the piercing member hub 408 and piercing member 402 (or needle) remaining by simply removing the insertion device 500 from the skin surface. This automatic release feature also minimizes potential patient contact with the piercing member 402 (or needle) of the insertion set 400, or the like.

In preferred embodiments, the insertion set 400, or the like, is adapted to  
10 tightly fit within a cavity 514 (or receiving structure) of the carrier body 504. The cavity 514 of the carrier body 504 includes guides 516 to orient the insertion set in a particular orientation and an expansion member 518 in the center bottom interior of the cavity 514 of the carrier body 504 to engage with the piercing member hub 408 (or needle hub) of the insertion set 400, or the like. The  
15 piercing member hub 408 of the insertion set 400, or the like, includes a center section 410 that engages with the expansion member 518 with a slight interference fit. The interference fit expands the center section 410 of the piercing member hub 408 slightly to expand and press the piercing member hub 408 against the sides of the cavity 514 of the carrier body 504 to firmly secure the  
20 insertion set 400, or the like, within the cavity 514 of the carrier body 504. The tight fit of the insertion set 400, or the like, in the carrier body 504 substantially prevents the insertion set 400, or the like, from being dislodged when the insertion device 500 is activated to improve insertion of the insertion set 400, or the like, on the skin. However, the tight fit also prevents the insertion set 400, or  
25 the like, from being ejected if the insertion device 500 is inadvertently activated when it is not pressed against the skin surface. In preferred embodiments, the insertion device 500 is configured to have guides 516 and an expansion member 518 to work with existing insertion sets 400, or the like. However, in alternative embodiments, the insertion set 400, or the like, may be modified to have a  
30 piercing member base, housing or the like that includes slots (not shown) for receiving guides and expanding members of the insertion device 500 to improve the connection between the insertion device 500 and the insertion set 400, or the

like. In further alternative embodiments, the guides and expansion members may be formed on the insertion set 400, or the like, and the corresponding guide slots and expanding sections may be formed on the insertion device 500.

5       The illustrated embodiment employs a dual trigger activation structure to minimize the ability of the insertion device 500 to be unintentionally activated. As illustrated, the barrel 502 of the insertion device 500 includes two outwardly extending guide channels 520 and 522 on the side of the barrel 502. The guide channels 520 and 522 extend from the base 524 of the barrel 502 up to portal  
10 openings 526 and 528 in the side of the barrel 502. The dual trigger buttons 510 and 512 are carried on opposite sides of the seating flange 506 at the end of the carrier body 504. Each trigger button 510 and 512 is biased outward from the side of the seating flange 506 by a trigger spring 530 and 532 between the end of the trigger buttons 510 and 512 and the side of the seating flange 506. When the  
15 carrier body 504 of the insertion device 500 is locked in the firing position (or retracted position), the trigger buttons 510 and 512 are pushed out by the trigger springs 530 and 532 to extend out of the portal openings 526 and 528. In this position, the trigger buttons 510 and 512 extend beyond the bottom of the guide channels 520 and 522, which prevents the trigger buttons 510 and 512 from  
20 moving down the guide channels 520 and 522. To activate the insertion device 500, the user must depress both trigger buttons 510 and 512 so that the trigger buttons 510 and 512 can then slide along the bottom of the guide channels 520 and 522, which in turn allows the carrier body 504 to move down along the barrel 502 until the insertion set 400, or the like, is inserted. In preferred embodiments,  
25 the portal openings 526 and 528 and the end of the guide channels 520 and 522 terminating at the portal openings 526 and 528 are rounded to match the shape of the trigger buttons 510 and 512. This tends to minimize the resisting pressure on the trigger buttons 510 and 512 during depression of the trigger buttons 510 and 512. However, in alternative embodiments other portal opening and guide  
30 channel end shapes, such as beveled, squared, polygonal, or the like, may be used.



The end of the carrier body 504 having the assembly rim 505 is connected to a release button 508 that can be depressed or slightly extended relative to the carrier body 504. The release button 508 includes engagement tabs 550 and lock teeth 552 (see Figs. 35 and 36) that engage with carrier slots 554 and carrier locks 556 (see Figs. 36 and 38) to lock the release button 508 to the carrier body 504. The lock teeth 552 engage with the carrier locks 556 (see Figs. 36 and 38) to permit an amount of movement of the lock teeth 552 along the carrier locks 556 to allow the release button 508 to be depressed to release an insertion set from the carrier body 504. The release button 508 is also slightly extended away from the carrier body 504 when an insertion set 400 is placed in the interior cavity 514 of the carrier body 504 to permit seating of the insertion set 400. Engaging the release button 508 with the carrier body substantially prevents the compression slots 509 and assembly rim 505 from compression and inhibits release of the carrier body 504 from the barrel 502 of the insertion device 500.

The release button 508 is depressed to release the insertion set 400, or the like, from the carrier body 504 of the insertion device 500. The release button 508 pushes the insertion set 400, or the like, out of the cavity 514 of the carrier body 504 sufficiently enough to release the insertion set 400, or the like, from the guides 516 and the expanding member 518 in the cavity 514 and leave the inserted insertion set 400, or the like, on the skin. Alternatively, the release button 508 may be activated to release an insertion set 400, or the like, from the carrier body 504 prior to the insertion set 400, or the like, being inserted by the insertion device 500. The release button 508 also includes a ramp portion 534 (or other trigger mechanism) that is adapted to bend or adjust the piercing member hub 408 (or needle hub) of the insertion set 400, or the like, to allow the piercing member hub 408 and piercing member 402 (or needle) to be released and separated from the insertion set 400, or the like, when the insertion set 400, or the like, has been inserted and the insertion device 500 is lifted off the skin. This can be accomplished by separating the elements of the insertion set 400, or the like, so that only the insertion set, or the like, housing and tubing (or wiring or the like) are left in contact with the skin. The ability to remove the piercing member hub

408 and piercing member 402 is preferably facilitated by the adhesive 406 of the insertion set 400, or the like, that attaches to the skin to provide sufficient tension to allow for separation of the piercing member hub 408 and the piercing member  
5 402 from the rest of the insertion set 400, or the like, without dislodging the insertion set 400, or the like. In preferred embodiments, the insertion device 500 is adapted to work with an existing piercing member hub 408 on an insertion set 400, or the like. However, in alternative embodiments, the piercing member hub 408 and the connection between the piercing member hub 408 and the insertion  
10 set housing, or the like, is modified to work with the release mechanism of the insertion device 500.

In preferred embodiments, the release button 508 is biased in position by a plastic or metal spring. However, in alternative embodiments, the release button 508 may be manually reset by engaging and disengaging detents or using other  
15 elastomeric materials to bias the release button 508 in position relative to the barrel 502 and the carrier body 504. In preferred embodiments, pulling up the release button 508 (or extending it away from the assembly port 503 of the barrel 502) pulls the carrier body 504 to the retracted position in the barrel 502, where it is locked in place by triggers 510 and 512 engaging the portal openings 526 and  
20 528. This procedure separates the piercing member hub 408 and piercing member 402 from the housing of the insertion set 400, or the like. This has the advantage of removing the piercing member 402 and piercing member hub 408 to minimize the opportunity of a user being stuck by the piercing member 402.

Figs. 40a-40g illustrate one method of insertion of an insertion set 400  
25 with the insertion device 500 in accordance with an embodiment of the present invention. The user first cleans and sterilizes an insertion site on the skin. Next, the user makes sure the insertion device 500 has the carrier body 504 in the advanced position to avoid unintentional activation of the insertion device 500 before placement on the skin. As shown in Fig. 40a, the user places the insertion  
30 set 400 in the cavity 514 of the carrier body by aligning the tubing (or wire leads or the like) with the slot 536 in the carrier body 504 and the slot 538 in the barrel 502 of the insertion device 500. The user presses against the piercing member

guard 414 (or needle guard) to seat the piercing member hub 408 (or needle hub) and the insertion set 400 in the cavity 514 of the carrier body 504. As shown in Fig. 40b, the user removes the adhesive backing 416 covering the adhesive 406 on the rim 404 of the insertion set 400. It is preferred that the piercing member guard 414 is not removed at this point to avoid unintentional sticks by the piercing member 402, and minimize or avoid contact with the adhesive 406. As shown in Fig. 40c, the user presses against the piercing member guard 414 to move the carrier body 504 from the advance position to the retracted position, at which point the trigger buttons 510 and 512 will extend out of the portal openings 526 and 528 to extend beyond the guide channels 520 and 522 to lock the carrier body 504 in the retracted position. Next, as shown in Fig. 40d, the user removes the piercing member guard 414 (normally by twisting) to expose the piercing member 402 while maintaining the insertion set 400 within the carrier body 504. Then, as shown in Fig. 40e, the user places the surface seat 501 of the barrel 502 of the insertion device 500 with the insertion set 400 over the insertion site on the skin. The user depresses the two trigger buttons 510 and 512 through the portal openings 526 and 528 sufficiently for the trigger buttons 510 and 512 to slide down along the guide channels 520 and 522 to insert and install the insertion set 400 at the insertion site on the skin. As shown in Fig. 40f, the user depresses the release button 508 to release the insertion set from the cavity 514 of the carrier body 504. Finally, as shown in Fig. 40g, the user removes the insertion device 500, while maintaining installation of the insertion set 400. In alternative embodiments, the user may extend the release button 508 to lift off the piercing member hub 408 and piercing member 402, and maintain the remainder of the insertion set 400 at the insertion site on the skin. If the piercing member hub 408 and piercing member 402 are lifted off the device, the user should re-install the piercing member guard 414 prior to removal of the remaining set from the insertion device 500.

Figs. 41-46 illustrate an insertion device 600 in accordance with a third embodiment that is similar to the insertion devices shown in Figs. 1-34. The insertion device 600 includes a device housing end 601 and a carrier body 602

that has angled insertion contact surfaces 603 and 604. The angled insertion contact surfaces 603 and 604 enable the user to properly angle the insertion device 600 to insert an insertion set 700, or the like, at the proper insertion angle relative to the skin. An insertion set similar to the insertion set 700 is disclosed in U.S. Patent Application Serial No. 08/871,831 (PCT Application Serial No. US98/10832) to Van Antwerp et al. entitled "Disposable Sensor Insertion Assembly" or an insertion set that can be inserted at an angle as disclosed in U.S. Patent Application Serial No. 09/034,626 to Funderburk et al. entitled "Medication Infusion Set", both of which are herein incorporated by reference. Preferred embodiments of the insertion device 600 have angled insertion contact surfaces 603 and 604 that permit insertion of insertion sets, or the like, that are angled from 89.9 degrees to 25 degrees relative to the skin surface. In further embodiments, the angled insertion contact surfaces 603 and 604 may handle even shallower angles down to approximately 10 degrees relative to the skin surface.

The key is the angled insertion contact surfaces 603 and 604 mirrors the insertion angle of the insertion set 700, or the like, so that the piercing member 702 (or needle) of the insertion set 700, or the like, is in axial alignment in the direction of movement of the carrier body 602 of the insertion device 600. This permits an insertion device designed primarily for use with a 90 degree insertion set, or the like, to be modified to work with angled insertion sets 700, or the like, by modification of the angle of the angled insertion contact surfaces 603 and 604. In addition, it is preferred that the piercing member 702 of the insertion set 700, or the like, be slightly off-center from the center axis of the carrier body 602 to permit easy removal of the insertion device 600 once the insertion set 700, or the like, has been inserted. Preferred embodiments of the present invention include a carrier body 602 with a receiving structure that includes a recess 606 and bore 608 on one side of the carrier body 602. The recess 606 is adapted to hold the piercing member hub 704 by a slight interference fit and the bore 608 is adapted to hold the insertion tubing or transmitter hub 706 of the insertion set 700, or the like. In other embodiments for the insertion sets such as infusion sets with tubing (or sensor sets with wire leads already connected to a sensor) the bore 608 may be

open on one side (not shown) to permit insertion and removal of the infusion tubing (or wire leads), but closed of sufficiently to securely hold and grasp the insertion tubing or transmitter hub 706 that connects the tubing or wire leads to the housing of the insertion set 700, or the like.

Fig. 47 illustrates an insertion device 800 that is adapted for inserting insertion sets, or the like, at angles that are generally less than or equal to 10 degrees relative to the skin surface after insertion of the insertion set, or the like. This embodiment includes a pair of pinchers 802 and 804 that grasps the skin.

10 The pinchers 802 and 804 pinches (or bunches) up the skin in front of a carrier body 806 holding an insertion set, or the like. Once the skin is pinched (or bunched up), the user depresses an activation button and the insertion set, or the like, is inserted into the skin. In alternative embodiments, the user presses the pinchers 802 and 804 closer together to activate the insertion device 800. After

15 insertion, the user releases the pinchers 802 and 804 and removes the insertion device 800 from the insertion set, or the like. The effect of this embodiment is to raise the skin so that the actual insertion angle of the piercing member relative to the side of the raised (or pinched) area of skin ranges from 10 degrees to 90 degrees so that the piercing member is inserted in manner similar to the

20 embodiments described above. However, when the pinched skin is released, the piercing member is left in the skin at a shallow angle between 0 and 10 degrees. The amount of pinching and the height of the pinch must be carefully controlled to assure that the insertion set, or the like, is inserted at the proper depth and location in the skin tissue. One example of an insertion set that can be inserted at

25 an angle as disclosed in U.S. Patent Application Serial No. 09/034,626 to Funderburk et al. entitled "Medication Infusion Set", which is herein incorporated by reference.

The embodiments shown in Figs. 1-48 (d) generally utilize a spring force to activate the driver to move the carrier body from a retracted position to an

30 advanced position. However, alternative embodiments may use other devices such as air springs, elastomeric foams, compressed gas, hydraulics, pyrotechnics or the like. Figs. 49-53 (d) show an insertion device 900 in accordance with a

fifth embodiment of the present invention. The insertion device may include many of the same components and may operate in a manner similar to that shown and described in the embodiments of Figs. 1-48 (d) above. Accordingly,

5 description of like components is omitted here.

The insertion device includes a device housing 902, a carrier body 904, a spring drive 906, and a release button 908. The insertion device housing 902 includes an angled end 910 that allows a user to select an insertion angle of an insertion set 950. The carrier body 904 includes a receiving end 912 to secure the  
10 insertion set 950 to the insertion device 900. The structure of the receiving end 912 of the carrier body 904 conforms to the shape of the angled end 910 of the device housing 902. Thus, when the carrier body 904 is in a fully advanced position (see Fig. 51 (e)), the angled end 910 provides a stable insertion angle that is not dislodged as the carrier body 904 moves from the retracted position to the  
15 advanced position.

The angled end 910 of the device housing 902 provides flexibility in the selection of the insertion angle of a piercing member 952 (such as a needle or the like) of an insertion set 950. Preferably, the angled end 910 of the device housing 902 allows for an insertion angle that is between and including  $10^{\circ}$  to  $90^{\circ}$ .  
20 However, in alternative embodiments, angles greater than  $0^{\circ}$  and between  $10^{\circ}$  or angles including  $90^{\circ}$  may be possible by modifications to the angled end 910 of the device housing 902.

As shown in Figs. 52 (a)-(f) and 53 (a)-(d), preferred embodiments of the angled end 910 include multi-planar structures for providing flat contact  
25 structures at specific insertion angles to permit insertion angles in the range of  $20^{\circ}$  to  $45^{\circ}$ . However, other angles as described above may be used. In particular embodiments, the angled end 910 includes at least two planar surfaces 914 and 916 to allow insertion at two specific angles. However, in alternative embodiments, additional planar surfaces, up to 10 or more, may be used. In  
30 preferred embodiments, the planar surfaces 914 and 916 are connected to each other by curved portions 918 to facilitate switching between various planar surfaces 914 and 916. This also allows the user to select angles between the

planar surfaces 914 and 916. In alternative embodiments, the angled end 910 is formed as a curve to allow the user to select any insertion angle within the selectable range as described above.

5           The receiving end 912 of the carrier body 904 is configured to fit within the angled end 910 of the device housing 902 so that it will not interfere with the insertion of an insertion set 950 as the carrier body 904 moves from a retracted position to an advanced position. In preferred embodiments, the receiving end 912 of the carrier body 904 is slightly recessed relative to the angled end 910 of  
10   the device housing 902 when the receiving end 912 of the carrier body 904 is in the advanced position. In other embodiments, the receiving end 912 includes the same multi-planar, or other structures, to match the angled end 910 when the receiving end 912 of the carrier body 904 is in the advanced position.

          A locking mechanism 920 for use with the insertion device 900 is shown  
15   in Figs. 53 (a)-(d). The locking mechanism 920 is used to secure an insertion set 950 to the receiving end 912 of the carrier body 904. In particular embodiments, the locking mechanism 920 includes a lever arm 922 having teeth 924. The lever arm 922 of the locking mechanism 920 is coupled to the receiving end 912 of the carrier body 904 and is biased in a locking position by a spring 926 coupled  
20   between the lever arm 922 and the receiving end 912 of the carrier body 904. In alternative embodiments, the spring 926 may be replaced with another biasing element, such as elastomeric materials, foams, leaf springs, or the like.

          In other alternative embodiments, the locking structures described above for the other embodiments of insertion devices (see Figs. 1-48 (d)), may be used  
25   as the locking mechanism in this embodiment. In still other alternative embodiments, the lever arm 922 may be replaced with other structures, such as hinged members, snap in place members, slide and cover members, or the like. In other embodiments, the receiving end 912 of the carrier body 904 includes a locking mechanism having a removable locking member to be used with other  
30   modified insertion devices or other modified insertion sets. For instance, the locking mechanism may be separate and removable from the carrier body 904 so that different insertion sets may be inserted with a single insertion device. Thus,

when a different locking mechanism is connected to the receiving end 912 of the carrier body 904 of the insertion device 900, the insertion device 900 is then ready for use with different insertion sets.

5 Figs. 51 (a)-(e) and 53 (a)-(d), show a preferred insertion set 950 adopted for use with the insertion device 900. The insertion set 950 is formed to have mating holes 954 spaced and shaped to match the teeth 924 on the lever arm 922 of the locking mechanism 920. When the teeth 924 of the lever arm 922 are engaged with the mating holes 954 of the insertion set 950 and pressing towards  
10 the carrier body 904, the insertion set 950 is secured within the insertion device 900 for placement into a patient. As discussed above with the other embodiments, the locking mechanism 920 keeps the insertion set 950 from flying off of the insertion device 900 in the event of an accidental or premature activation, when the insertion device 900 is not in a position for placement of the  
15 insertion set 950 in the skin of a patient.

Figs. 51 (a)-(e) and 53 (a)-(d), show the operation of the insertion device 900. An insertion set 950 is loaded into the device 900 at the receiving end 912 of the carrier body 904. The user pushes down the end of the lever arm 922 of the locking mechanism 920 (as shown at a in Fig. 51 (a)) to raise the teeth 924 of the  
20 lever arm 922 of the locking mechanism 920. While the teeth 924 of the lever arm 922 are raised, the user places the insertion set 950 on a receiving surface 928 of the receiving end 912 of the carrier body 904. The user releases the end of the lever arm 922 of the locking mechanism 920 and the spring 926 closes the teeth 924 of the lever arm 922 into the mating holes 952 of the insertion set 950  
25 to secure the insertion set 950 in the locking mechanism 920 of the insertion device 900.

After securing the insertion set 950 in the insertion device 900, the user pushes the carrier body 904 of the insertion device 900 back towards the retracted position (in direction b as shown in Fig. 51 (b)) until the carrier body 904 slides  
30 into the retracted position (as shown in Fig. 51 (c)). The carrier body 904 is held securely in the retracted position by a temporary lock 928 attached to the release button 908 at the end of the device housing 902 of the insertion device 900. The



user may choose to trigger lock the carrier body 904 in the retracted position by rotating the release button 908 to prevent premature triggering of the carrier body 904 until the user is ready to insert the insertion set 950, as discussed above in the  
5 other embodiments.

Next, the user selects an insertion angle for the insertion set 950, by placing the angled end 910 of the device housing 902 of the insertion device 900 against the skin and rotating the device housing 902 about the patient's skin (see Figs. 51 (c) and 52 (a)-(f)) until an insertion angle is selected. Then the insertion  
10 device 900 is held firmly in place against the skin at the selected angle and the user depresses the release button 908 on the device housing 902 to release the carrier body 904. The carrier body 904 moves from the retracted position to an advanced position (in direction d as shown in Fig. 51 (d)) to insert the insertion set 950 into the patient's skin at the selected insertion angle. After inserting the  
15 insertion set 950 at the selected insertion angle, the user disengages the insertion set 950 from the insertion device 900 by depressing the end of the lever arm 922 (as shown at e in Fig. 51 (e)) to raise and disengage the teeth 924 of the lever arm 922 from the insertion set 950. Then the insertion device 900 is moved away from the patient's skin, to remove the insertion device 900 from the insertion set  
20 950 and leave the insertion set 950 placed in the patient's skin (as shown in Fig. 51 (e)).

Figs. 54-58 (f) show an insertion device 1000 in accordance with a sixth embodiment of the present invention. This embodiment is similar to the embodiment in Figs. 49-53 (d) but the device housing 1002 includes a separate  
25 rotatable end (or member) 1004, which is coupled to the device housing 1002 by pins 1006. This rotatable end 1004 replaces the angled end 910 of the previous embodiment. The rotatable end 1004 of this embodiment allows the device housing 1002 to rotate freely to provide a wider selection of the insertion angle for an insertion set 950 and yet also provide a larger contact area regardless of the  
30 insertion angle selected for greater stability. As shown in Figs 54-58 (f), the rotatable end 1004 has a flat contact surface 1008 that provides a larger contact area than that generally obtainable in the embodiment shown in Figs 49-53 (d).

Although the insertion device 1000 uses a larger contact surface and is more stable, the tradeoff to the design is that it is more complicated to manufacture since it uses multiple parts.

5           To use the insertion device 1000, the user loads and secures the insertion set 950 in the insertion device 1000, and moves a carrier body 1010 to the retracted position, as described above. Then, the user places the flat contact surface 1008 of the rotatable end 1004 against the skin. The user rotates the device housing 1002 about the pins 1006 of the rotatable end 1004 to vary the  
10 insertion angle. Next the user activates the insertion device 1000 to move the carrier body 1010 and the insertion set 950 from the retracted position to the advanced position. In preferred embodiments, the rotatable end 1004 allows for an insertion angle from 20° to 45°, as shown in Figs. 58 (a)-(f), which may be selected by simply rotating the insertion device housing 1002 about the pins 1006  
15 to achieve the insertion angles. However, in alternative embodiments angles between 0° and 20°, or over 45° may be obtainable with the rotatable end 1004 by simply allowing a greater range of rotation of the rotatable end 1004 relative to the device housing 1002 about the pins 1006.

Fig. 59 shows an insertion device 1100 in accordance with a seventh  
20 embodiment of the present invention. The insertion device 1100 is similar to the devices described above and may be combined with and modified to work with the devices described above and shown in Figs. 1-58 (f).

The insertion device 1100 omits a spring for driving the carrier forward and instead is adapted to manually drive a carrier body 1102 forward to insert an  
25 insertion set into a patient's skin. The carrier body 1102 of the insertion device 1100 includes a plunger body 1104 with a receiving end 1106 to secure the insertion set to the insertion device 1100 and to insert the insertion set into the patient's skin. A device housing 1108 holds the carrier body 1102 within the device housing 1108 and allows for the movement of the carrier body 1102  
30 within the device housing 1108 between an advanced position and a retracted position. The receiving end 1106 of the carrier body 1102 holds the insertion set so that it will not fly off during activation. A press surface 1110 that is activated

by thumb or hand pressure is used to push the carrier body 1102 from the retracted position to the advanced position within the device housing 1108. As the receiving end 1106 of the carrier body 1102 is pressed towards the advanced position, it must pass one or more detentes 1112 that inhibit premature and/or accidental movement of the carrier body 1102. The detent 1112 sets a threshold force level that must be applied to insert a piercing member (or needle) of an insertion set at a controlled rate and speed. Once the threshold level to pass the detent 1112 is overcome, the carrier body 1104 moves to the advanced position with sufficient speed to insert the insertion set in the skin of the patient. In preferred embodiments, the detent 1112 acts only on the receiving end 1106. In alternative embodiments, the detent 1112 acts on the receiving end 1106 and the plunger 1104 to provide interference during the entire movement of the carrier body from the retracted position to the advanced position. In other embodiments, the threshold level is lower for the plunger 1104 than the receiving end 1106. In still other embodiments, only part of the plunger 1104 and/or the receiving end 1106 may have different threshold levels along all or part of the components as they slide past the detent ---.

To use the insertion device 1100, a user loads an insertion set into the receiving end 1106 of the carrier body 1102 and pulls back against the carrier body 1102 to move it to the retracted position past the detent 1112. The detent 1112 within the device housing 1108 holds the carrier body 1102 in the retracted position until it is ready to be released for inserting the insertion set into the patient's skin. Next the user positions the insertion device 1100 against the patient's skin. The user applies pressure to the press surface 1100 of the carrier body 1102 and pushes on the carrier body 1102 with a firm constant force to allow the carrier body 1102 to move to the advanced position, as the force applied to the carrier body 1102 exceeds the threshold level for the detent 1112, so that the insertion set is inserted into the patient's skin. The user then removes the insertion set from the receiving end 1106 of the carrier body 1002. This manual operation provides some users with desired manual control over the insertion process. As shown in Fig. 60, an insertion device 1114 is similar to the insertion

device 1100, but utilizes a different device housing and receiving end on the carrier body to accommodate different insertion sets.

5 While the description above refers to particular embodiments of the present invention, it will be understood that many modifications may be made without departing from the spirit thereof. The accompanying claims are intended to cover such modifications as would fall within the true scope and spirit of the present invention.

10 The presently disclosed embodiments are therefore to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims, rather than the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.

WHAT IS CLAIMED IS:

1. An insertion device for inserting at least a portion of at least one  
piercing member of an insertion set through the skin of a patient, the insertion  
5 device comprising:  
a device housing including an angled end of the housing device to support  
a selectable insertion angle of the insertion device relative to the skin of the  
patient;  
a carrier body slidably received within the device housing for movement  
10 between an advanced position and a retracted position, the carrier body includes a  
receiving structure to support the insertion set in a position with at least one  
piercing member oriented for insertion through the skin of the patient at the  
selectable insertion angle relative to the skin of the patient upon movement of the  
carrier body from the retracted position to the advanced position;  
15 a driver operatively coupled between the device housing and the carrier  
body to urge the carrier body from the retracted position toward the advanced  
position to place at least a portion of the at least one piercing member of the  
insertion set through the skin of the patient to install the insertion set to the  
patient; and  
20 wherein the receiving structure of the carrier body is removable from the  
insertion set while maintaining the installation of the insertion set to the patient.
2. An insertion device according to claim 1, wherein a portion of the  
angled end includes a multi-planar surface to facilitate the selection of selectable  
25 insertion angle.
3. An insertion device according to claim 1, wherein the angled end  
is a separate-rotatable member connected to the device housing by at least one pin  
to facilitate the movement of the device housing about the separate-rotatable  
30 member and support the selectable insertion angle of the insertion device.

4. An insertion device according to claim 3, wherein the separate-rotatable member of the device housing includes a contact surface to provide a substantially flat contact surface for the insertion device against the patient's skin.

5. An insertion device according to claim 1, wherein the piercing-member insertion angle is from 20 degrees to 45 degrees.

6. An insertion device according to claim 1, wherein the piercing-member insertion angle is greater than 0 and less than or equal to 20.

7. An insertion device according to claim 1, wherein a portion of the angled end forms a curved opening with two arms surrounding the receiving structure, and wherein the two arms extend beyond the receiving structure of the carrier body to support the device housing at the selectable insertion angle of the insertion device.

8. An insertion device according to claim 1, wherein the receiving structure has a skin contacting surface with a multi-planar front end, wherein the multi-planar front end of the receiving structure is shaped to be co-extensive with the angled end of the device housing when the carrier body is in the advanced position to facilitate insertion at the selectable insertion angle of the device housing relative to the patient's skin.

9. An insertion device according to claim 8, wherein the receiving structure includes a locking mechanism to engage at least a portion of the insertion set.

10. An insertion device according to claim 9, wherein the locking mechanism includes teeth, wherein the teeth are coupled to the insertion set and secured in position by a spring member to facilitate locking and placement of the  
5 piercing member at the selectable insertion angle of the device housing relative to the patient's skin.

11. An insertion device according to claim 1, wherein the selectable insertion angle relative to the skin is about 90 degrees.

10

12. An insertion device according to claim 1, wherein the selectable insertion angle relative to the skin is between 90 degrees and 10 degrees.

13. An insertion device according to claim 1, wherein the selectable  
15 angle relative to the skin after insertion is greater than 0 and less than or equal to 10 degrees.

14. An insertion device according to claim 1, wherein the insertion set is a transcutaneous insertion set.

20

15. An insertion device according to claim 1, wherein the insertion set is a subcutaneous insertion set.

16. An insertion device according to claim 1, wherein the insertion set  
25 rests mainly on the surface of the skin after insertion.

17. An insertion device according to claim 1, wherein the insertion set is fully implanted in the skin of the patient.

18. An insertion device according to claim 1, wherein the at least one  
30 piercing member is a needle.

19. An insertion device according to claim 1, wherein the at least one piercing member is at least one needle.

5 20. An insertion device according to claim 1, wherein at least one needle is a micro-needle.

21. An insertion device according to claim 1, wherein the insertion set is an infusion set.

10

22. An insertion device according to claim 1, wherein the insertion set is a sensor set.

23. An insertion device according to claim 1, further including a  
15 trigger mechanism that actuates the driver.



24. An insertion device for inserting at least a portion of at least one piercing member of an insertion set through the skin of a patient, the insertion device comprising:

5 device housing means for holding parts of the insertion device, wherein the device housing means include angled end means for supporting a selectable insertion angle relative to the skin of the patient upon the movement of the angled end means and the placement of the insertion device relative to the skin of the patient;

10 carrier means slidably received within the device housing means for movement between an advanced position and a retracted position, wherein the carrier means includes receiving means for supporting the insertion set in a position with the at least one piercing member oriented for insertion through the skin of the patient at the selectable insertion angle relative to the skin of the patient upon movement of the carrier means from the retracted position to the advanced position;

driver means operatively coupled between the device housing means and the carrier means to urge the carrier means from the retracted position toward the advanced position to place at least a portion of the at least one piercing member of the insertion set thorough the skin of the patient to install the insertion set to the patient; and

wherein the receiving means of the carrier means is removable from the insertion set while maintaining the installation of the insertion set to the patient.

25. An insertion device according to claim 24, wherein a portion of the angled end means includes multi-planar means for supporting the insertion device relative to the patient's skin to facilitate selection of the selectable insertion angle.

26. An insertion device according to claim 25, wherein a portion of the angled end means forms partially open curved means extending beyond the receiving means for supporting the piercing member against the patient's skin at  
5 the selected angle.

27. An insertion device according to claim 25, wherein the receiving means has a skin contacting means with a multi-planar front means, wherein the multi-planar front means of the receiving means is shaped to be co-extensive with  
10 the angled front means of the device housing means when the carrier means is in the advanced position to facilitate insertion at the selectable insertion angle of the device housing means relative to the patient's skin.

28. An insertion device according to claim 24, wherein the receiving  
15 means structure includes locking means to hold at least a portion of the insertion set.

29. An insertion device according to claim 28, wherein the locking means includes teeth, wherein the teeth are coupled to the insertion set and  
20 secured in position by spring means to facilitate the placement and locking of the piercing member at the selectable insertion angle of the device housing means relative to the patient's skin.

30. An insertion device according to claim 24, wherein the selectable  
25 insertion angle relative to the skin is about 90 degrees.

31. An insertion device according to claim 24, wherein the selectable insertion angle relative to the skin is between 90 degrees and 10 degrees.

32. An insertion device according to claim 24, wherein the selectable angle relative to the skin after insertion is greater than 0 and less than or equal to 10 degrees.
- 5
33. An insertion device according to claim 24, wherein the insertion set is a transcutaneous insertion set.
34. An insertion device according to claim 24, wherein the insertion set is a subcutaneous insertion set.
- 10
35. An insertion device according to claim 24, wherein the insertion set rests mainly on the surface of the skin after insertion.
- 15
36. An insertion device according to claim 24, wherein the insertion set is fully implanted in the skin of the patient.
37. An insertion device according to claim 24, wherein at least one piercing member is a needle.
- 20
38. An insertion device according to claim 37, wherein at least one piercing member is at least one needle.
39. An insertion device according to claim 37, wherein at least one needle is a micro-needle.
- 25
40. An insertion device according to claim 24, wherein the insertion set is an infusion set.
- 30
41. An insertion device according to claim 24, wherein the insertion set is a sensor set.

42. An insertion device according to claim 24, further including a trigger mechanism that actuates the driver.

5           43. An insertion device according to claim 24, wherein the insertion set is subcutaneous.

          44. An insertion device for inserting at least a portion of at least one piercing member of an insertion set through the skin of a patient, the insertion  
10 device comprising:

          a device housing to support the insertion device relative to the skin of the patient;

          a carrier body slidably received within the device housing for movement between an advanced position and a retracted position, the carrier body includes a  
15 receiving structure to support the insertion set in a position with at least one piercing member oriented for insertion through the skin of the patient upon movement of the carrier body from the retracted position to the advanced position;

          a locking mechanism to engage at least a portion of an insertion set and  
20 secure it to the receiving structure of the carrier body, and to substantially prevent the premature release of the carrier body before securing it in position against the patient's skin.

          a driver operatively coupled between the device housing and the carrier body to urge the carrier body from the retracted position toward the advanced  
25 position to place at least a portion of the at least one piercing member of the insertion set through the skin of the patient to install the insertion set to the patient; and

          wherein the receiving structure of the carrier body is removable from the insertion set while maintaining the installation of the insertion set to the patient.

30

45. An insertion device according to claim 44, wherein the locking mechanism includes a lever arm coupled with teeth to secure the insertion set to the receiving end of the carrier body and a spring coupled between the lever arm and the receiving end of the carrier body to bias the lever arm in a locking position and facilitate the placement of the piercing member in the patient's skin.

46. An insertion device for inserting at least a portion of at least one piercing member of an insertion set through the skin of a patient, the insertion device comprising:

- a device housing to support the insertion device relative to the skin of the patient;
- a carrier body slidably received within the device housing for movement between an advanced position and a retracted position, the carrier body includes a receiving structure to support the insertion set in a position with at least one piercing member oriented for insertion through the skin of the patient upon movement of the carrier body from the retracted position to the advanced position;
- a driver operatively coupled between the device housing and the carrier body to move the carrier body from the retracted position toward the advanced position to place at least a portion of the at least one piercing member of the insertion set through the skin of the patient to install the insertion set to the patient; and
- wherein the receiving structure of the carrier body is removable from the insertion set while maintaining the installation of the insertion set to the patient.

47. An insertion device according to claim 46, wherein the carrier body is a plunger to hold the insertion set and to insert it in the patient's skin by moving from the retracted position to the advanced position.

48. An insertion device according to claim 47, wherein the carrier body is coupled to a detent within the device housing, and wherein the detent has a level that must be overcome to permit and to facilitate the movement of the  
5 plunger from the retracted position to the advanced position with a controlled force and speed.

49. An insertion device according to claim 47, wherein the carrier body is adapted for use with different types of sets.  
10

50. An insertion device according to claim 46, wherein the distance traveled by the plunger within the device housing is equal to at least a distance required to fully insert the insertion set in the patient's skin that is at least equal to an implantable length of the piercing member.  
15

51. An insertion device according to claim 46, wherein the driver is a press surface coupled to a carrier body to allow pushing the plunger from the retracted position to the advanced position.

20 52. An insertion device according to claim 1, wherein the insertion device is removable from the insertion set.

53. An insertion device according to claim 52, wherein the insertion device is completely removable from the insertion set.  
25

54. An insertion device according to claim 1, wherein the insertion set is inserted to avoid contacting bone.

55. An insertion device according to claim 54, wherein the at least one  
30 piercing member terminates in flesh.

56. An insertion device according to claim 1, further including a safety structure on the carrier body that retains the insertion set during forward movement of the carrier body from the retracted position to the advanced position.

57. An insertion device according to claim 56, wherein the safety structure on the carrier body retains the insertion set upon completion of the forward movement of the carrier body to inhibit further forward motion of the insertion set.

58. An insertion device according to claim 1, wherein the insertion set adheres to the skin.

59. An insertion device according to claim 1, wherein an infusion tube is attached to the insertion set during insertion.

60. An insertion device according to claim 1, wherein the controlled force and speed that urges the carrier body from the retracted position to the advanced position is incapable of piercing bone.

61. An insertion device according to claim 24, wherein the insertion device is removable from the insertion set.

62. An insertion device according to claim 61, wherein the insertion device is completely removable from the insertion set.

63. An insertion device according to claim 24, wherein the insertion set is inserted to avoid contacting bone.

64. An insertion device according to claim 63, wherein the at least one piercing member terminates in flesh.

65. An insertion device according to claim 24, wherein the insertion set adheres to the skin.

5 66. An insertion device according to claim 24, wherein an infusion tube is attached to the insertion set during insertion.

67. An insertion device according to claim 24, wherein the controlled force and speed that urges the carrier body from the retracted position to the  
10 advanced position is incapable of piercing bone.

68. An insertion device according to claim 44, wherein the insertion device is removable from the insertion set.

15 69. An insertion device according to claim 68, wherein the insertion device is completely removable from the insertion set.

70. An insertion device according to claim 44, wherein the insertion set is inserted to avoid contacting bone.  
20

71. An insertion device according to claim 70, wherein the at least one piercing member terminates in flesh.

72. An insertion device according to claim 44, wherein the insertion  
25 set adheres to the skin.

73. An insertion device according to claim 44, wherein an infusion tube is attached to the insertion set during insertion.

30 74. An insertion device according to claim 44, wherein the controlled force and speed that urges the carrier body from the retracted position to the advanced position is incapable of piercing bone.



75. An insertion device according to claim 46, wherein the insertion device is removable from the insertion set.

5 76. An insertion device according to claim 75, wherein the insertion device is completely removable from the insertion set.

77. An insertion device according to claim 46, wherein the insertion set is inserted to avoid contacting bone.

10

78. An insertion device according to claim 77, wherein the at least one piercing member terminates in flesh.

79. An insertion device according to claim 46, wherein the insertion set adheres to the skin.

15

80. An insertion device according to claim 46, wherein an infusion tube is attached to the insertion set during insertion.

20 81. An insertion device according to claim 46, wherein the controlled force and speed that urges the carrier body from the retracted position to the advanced position is incapable of piercing bone.

82. An insertion set for insertion through the skin of a patient by an insertion device having a carrier body for movement between an advanced position and a retracted position, the carrier body of the insertion device including  
5 a receiving structure to support the insertion set in a position for insertion through the skin of the patient upon movement of the carrier body from the retracted position to the advanced position, and the insertion device having a driver that urges the carrier body from the retracted position toward the advanced position for insertion of the insertion set thorough the skin of the patient, the insertion set  
10 comprising:

at least one piercing member, wherein at least a portion of the at least one piercing member is insertable through the skin of the patient; and  
a set housing coupled to the at least one piercing member, wherein the set housing is shaped to fit within the carrier body of the insertion device to orient  
15 the at least one piercing member for placement through the skin of the patient of at least a portion of the at least one piercing member at an angle relative to the skin of the patient to install the insertion set to the patient, and  
wherein the set housing of the insertion set is removable from the receiving structure of the carrier body while maintaining the installation of the  
20 insertion set to the patient.

83. An insertion set according to claim 82, wherein the angle relative to the skin is about 90 degrees.

25 84. An insertion set according to claim 82, wherein the angle relative to the skin after insertion is between an angle greater than 0 and less than or equal to 10 degrees.

85. An insertion set according to claim 82, wherein the insertion set is  
30 a transcutaneous insertion set.

86. An insertion set according to claim 82, wherein the insertion set is a subcutaneous insertion set.

5 87. An insertion set according to claim 82, wherein the insertion set rests mainly on the surface of the skin after insertion.

88. An insertion set according to claim 82, wherein the insertion set is fully implanted in the skin of the patient.

10

89. An insertion set according to claim 82, wherein the at least one piercing member is a needle.

90. An insertion set according to claim 82, wherein the at least one  
15 piercing member is a plurality of needles.

91. An insertion set according to claim 90, wherein the plurality of needles are micro-needles.

20 92. An insertion set according to claim 82, wherein the insertion set is an infusion set.

93. An insertion set according to claim 82, wherein the insertion set is a sensor set.

25

94. An insertion set according to claim 82, wherein the insertion set is both an infusion set and a sensor set combined into an integral unit.

95. An insertion set according to claim 82, wherein the insertion  
30 device is removable from the insertion set.

96. An insertion set according to claim 95, wherein the insertion device is completely removable from the insertion set.

5 97. An insertion set according to claim 82, wherein the insertion set is inserted to avoid contacting bone.

98. An insertion set according to claim 97, wherein the at least one piercing member terminates in flesh.

10

99. An insertion set according to claim 82, wherein the insertion set adheres to the skin.

100. An insertion set according to claim 82, wherein an infusion tube is  
15 attached to the insertion set during insertion.

101. An insertion set according to claim 82, wherein the controlled force and speed that urges the carrier body from the retracted position to the advanced position is incapable of piercing bone.

20

102. An insertion set according to claim 82, wherein the angle relative to the skin is between 90 degrees and 10 degrees.

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FIG. 1

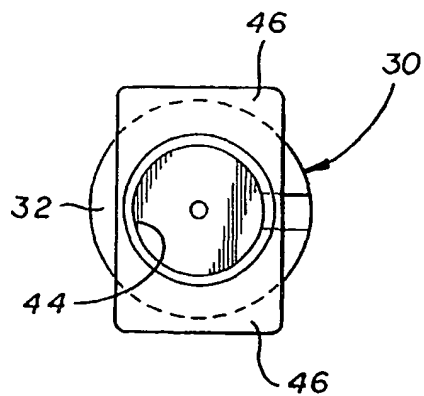
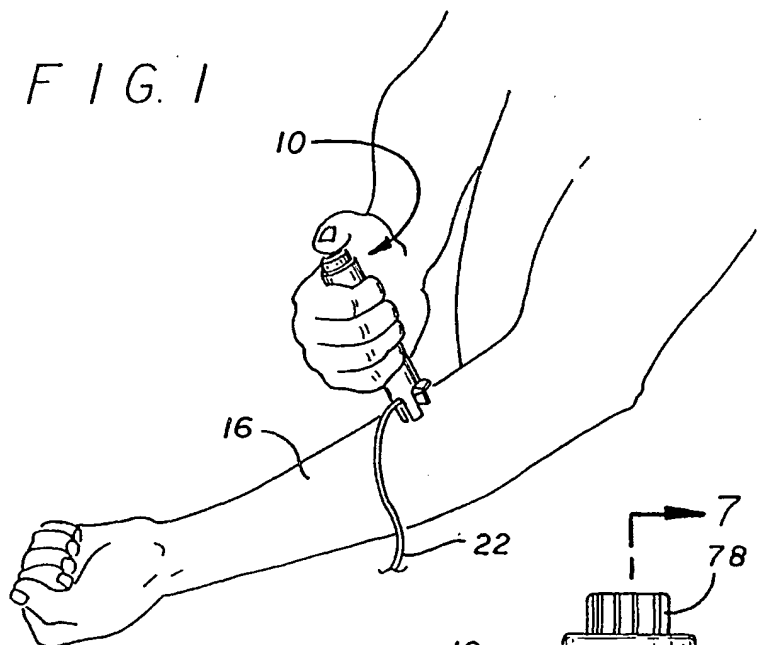
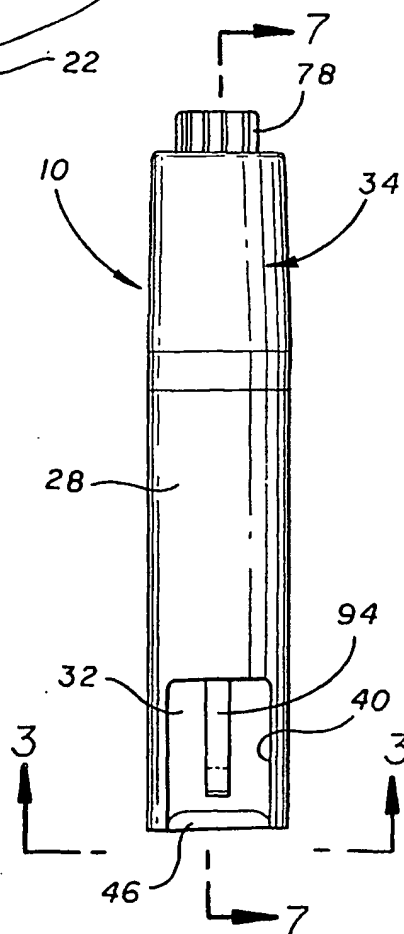


FIG. 3

FIG. 2



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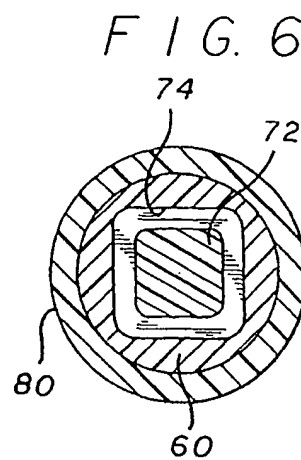
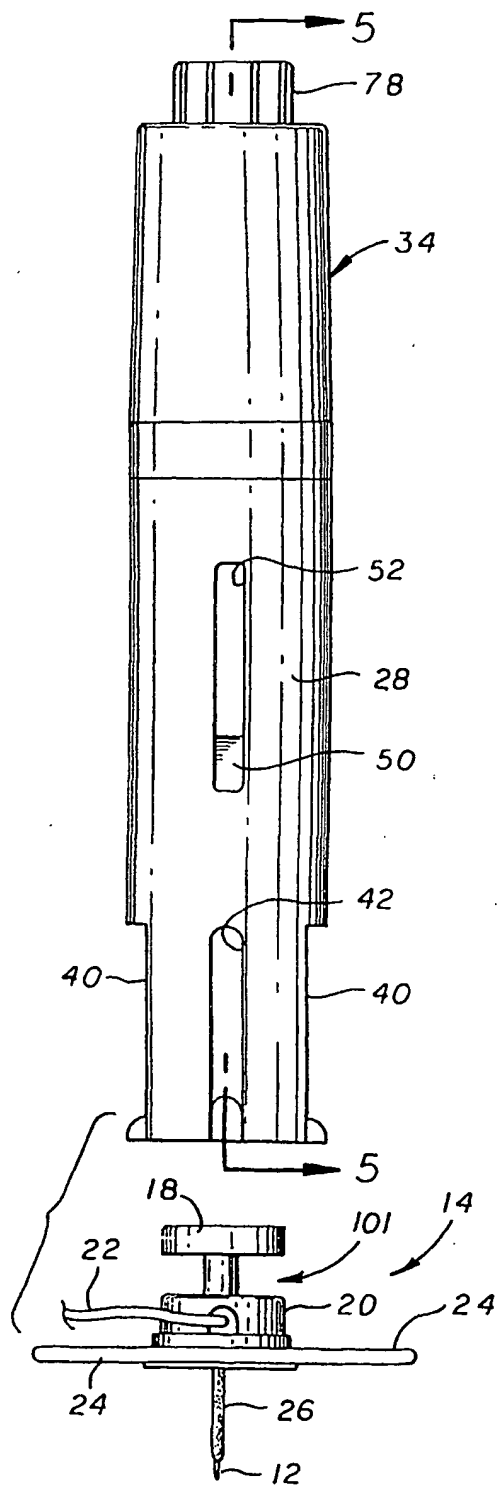


FIG. 4

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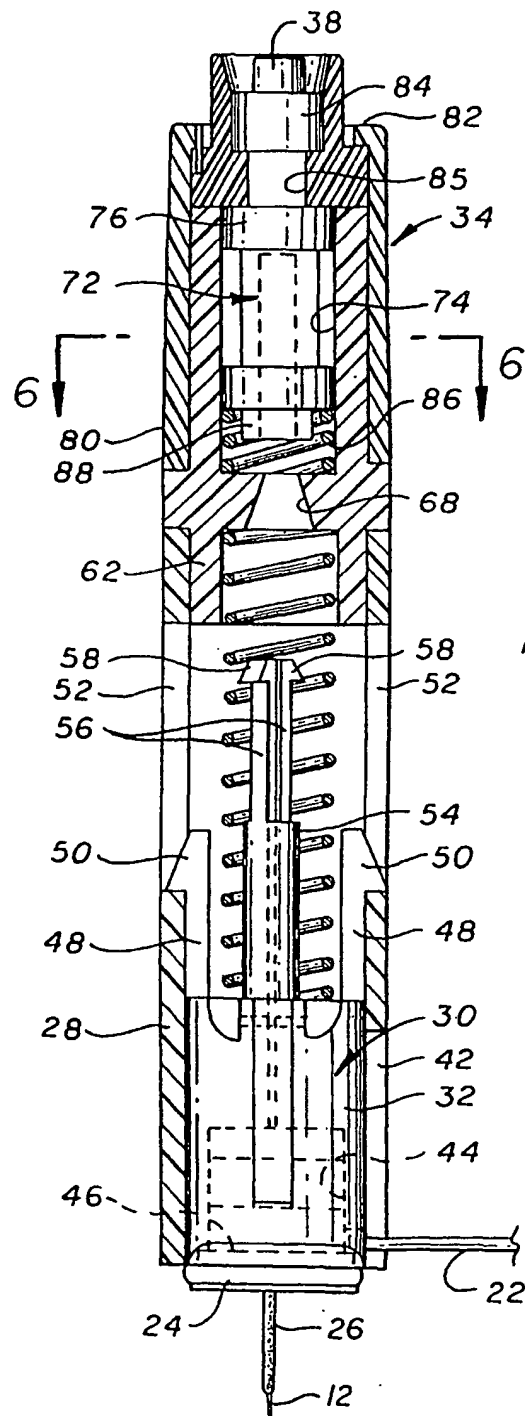


FIG. 5

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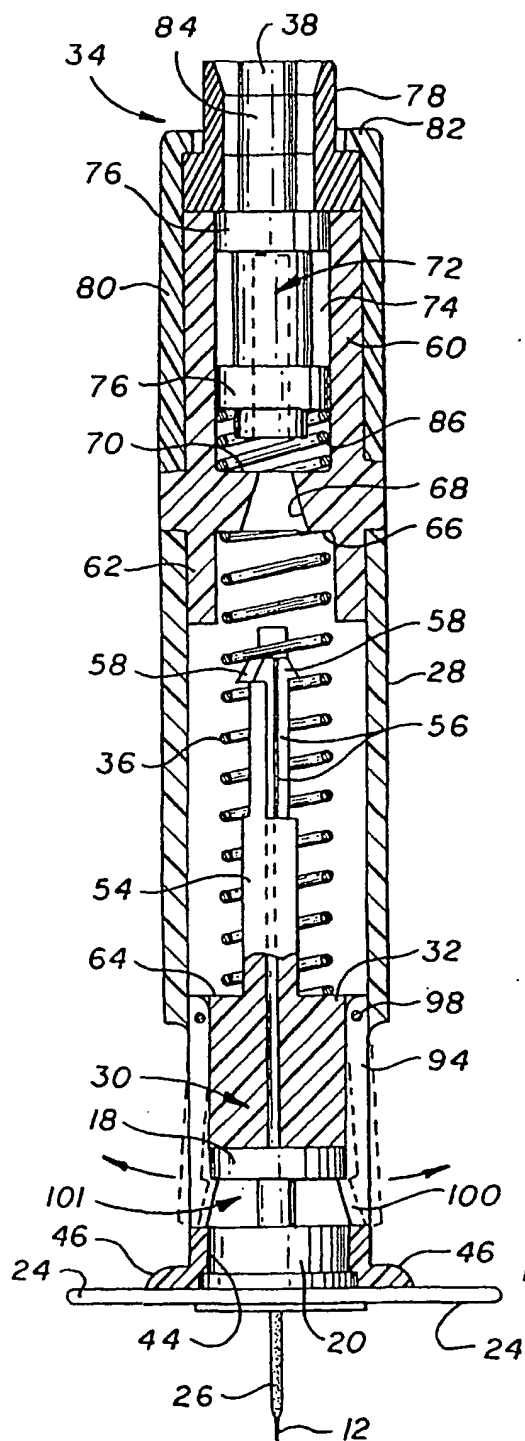


FIG. 7

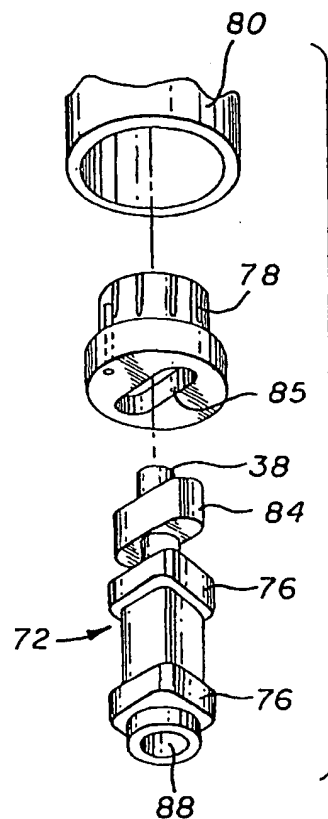


FIG. 8



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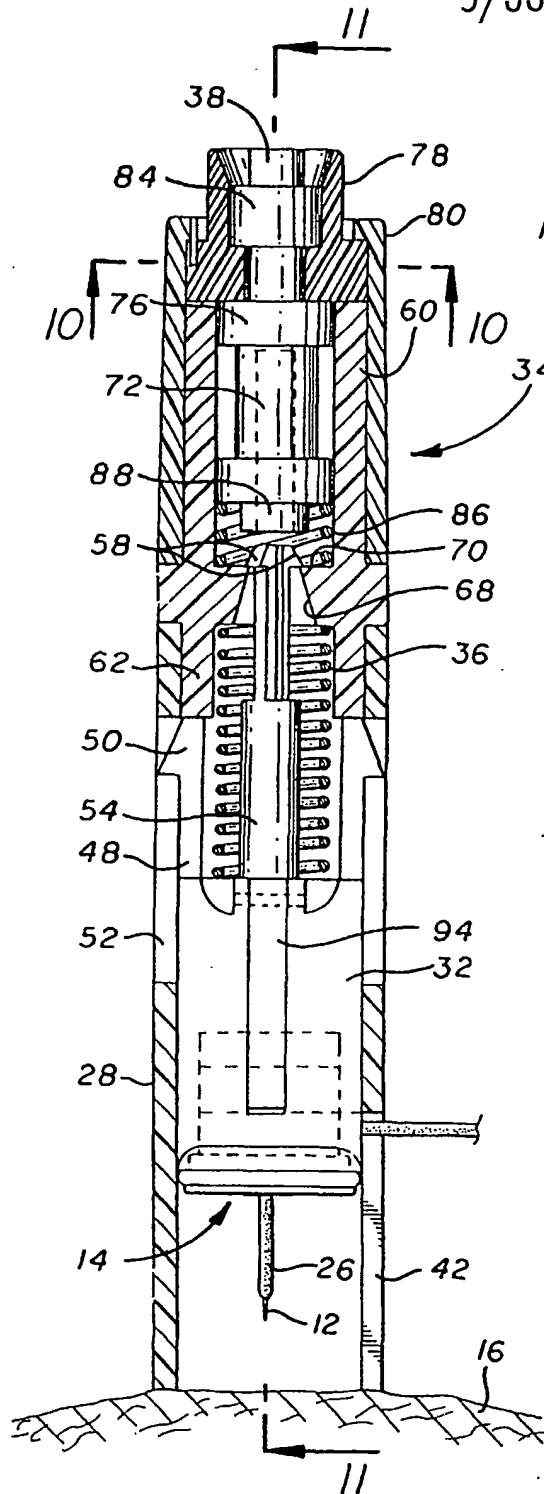
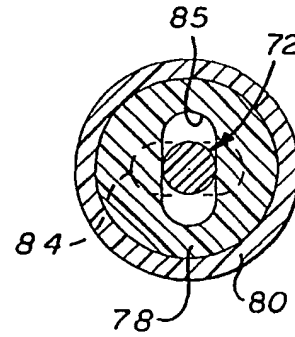


FIG. 9

FIG. 10



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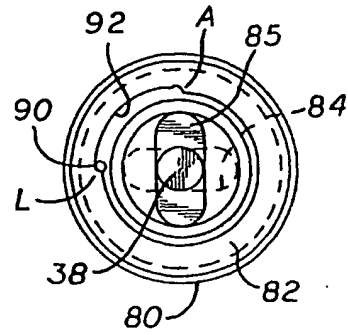
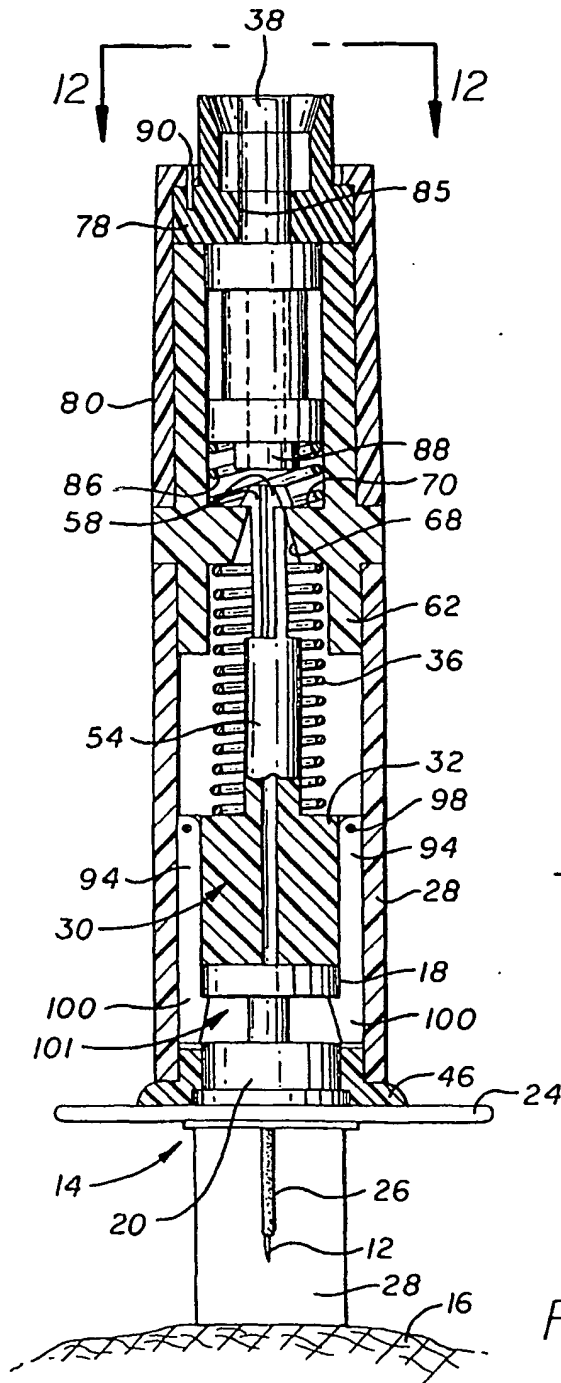


FIG. 12

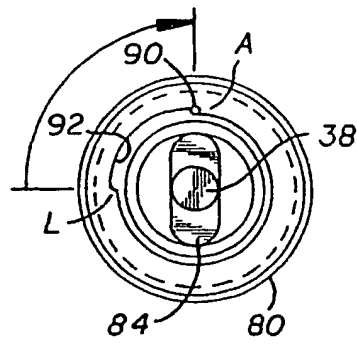
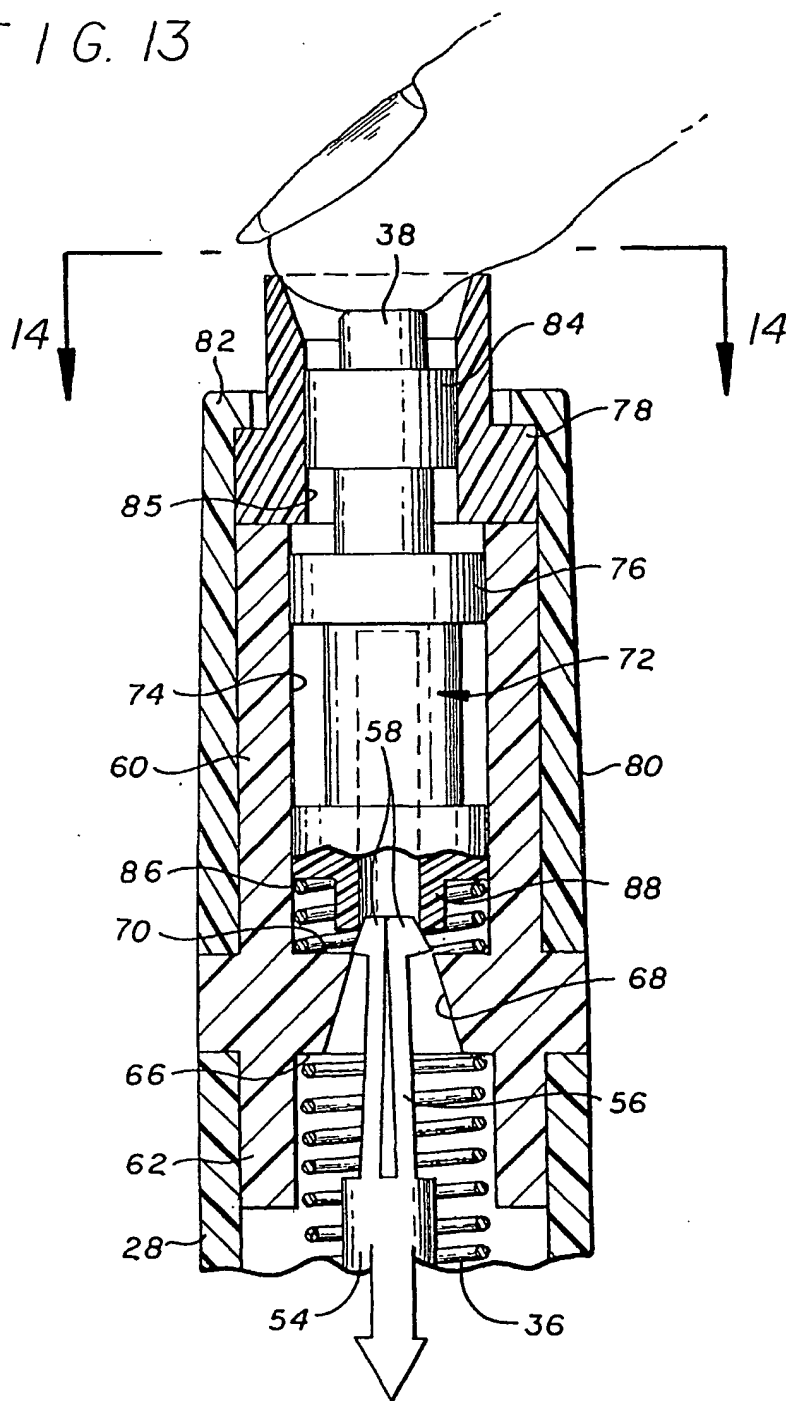


FIG. 14

FIG. 11

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FIG. 13



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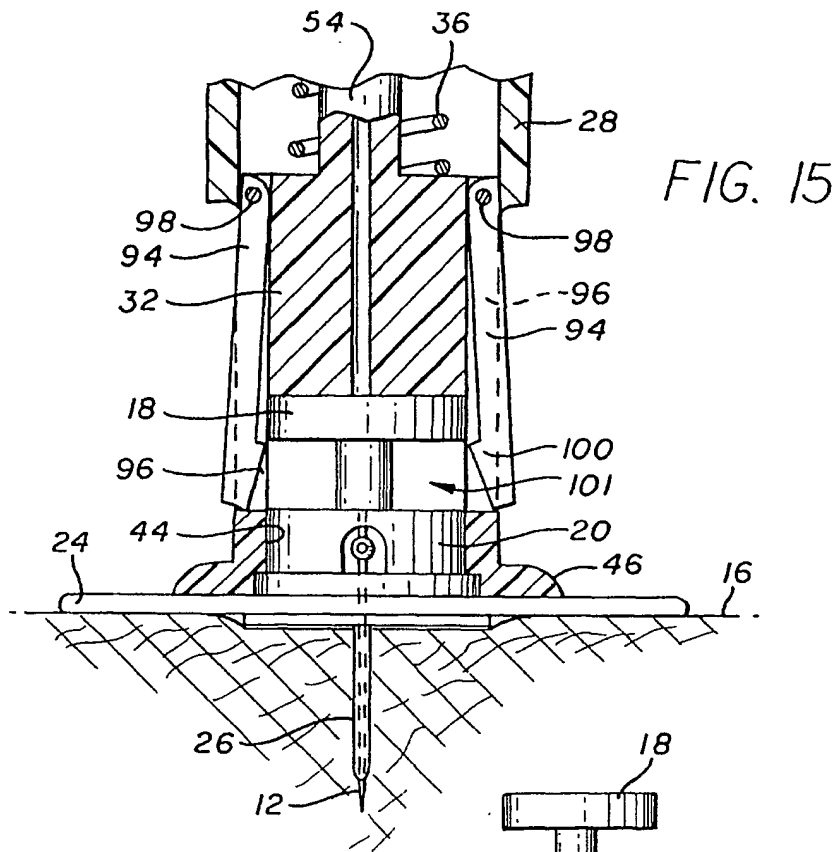
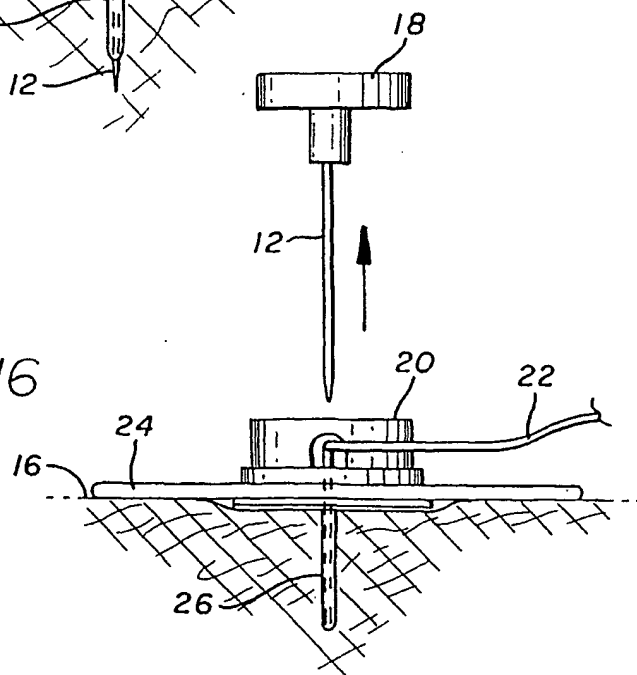
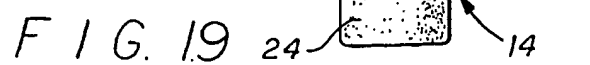
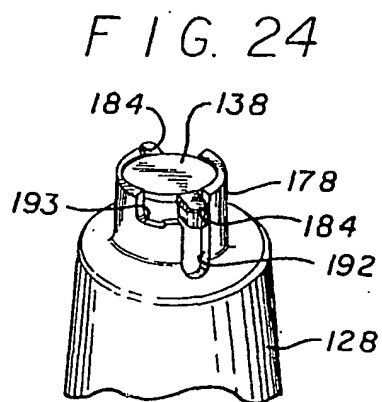
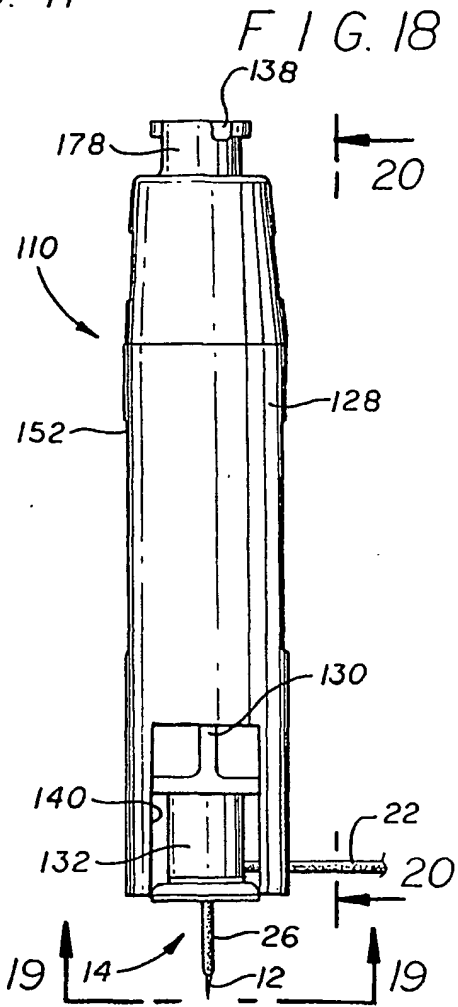
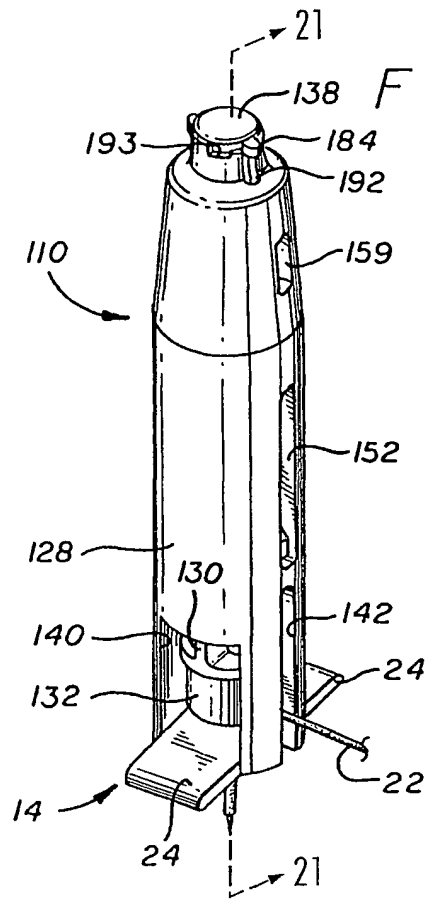


FIG. 16



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FIG. 20

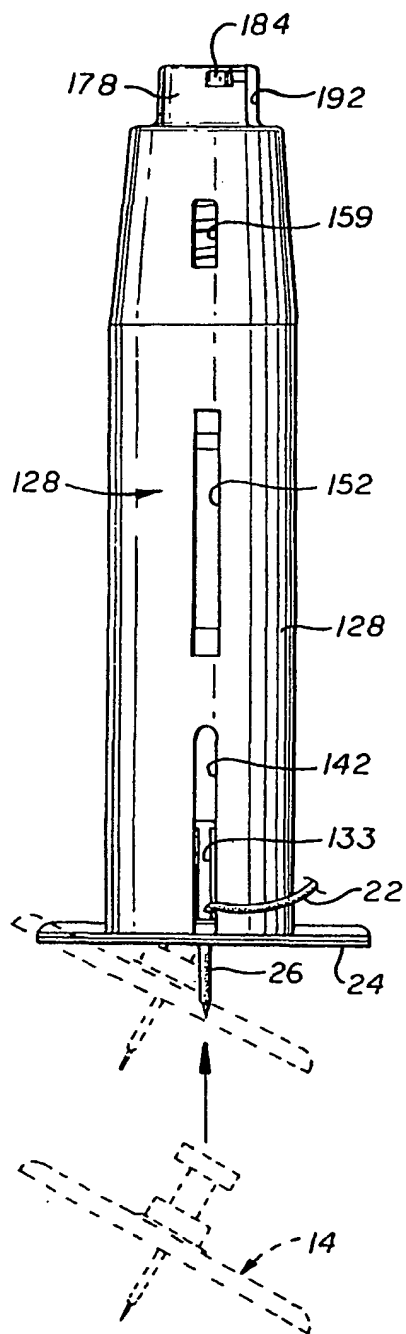
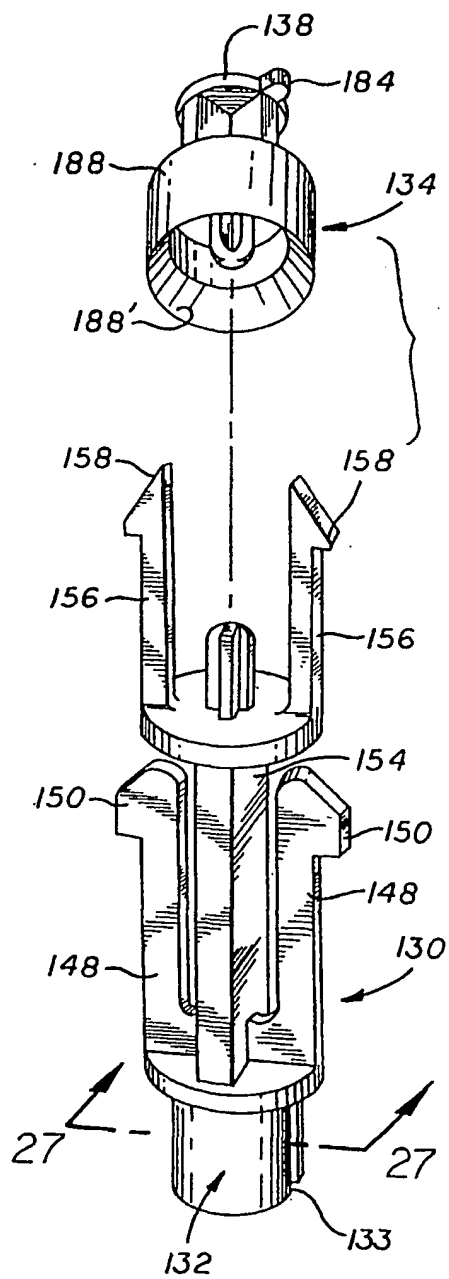


FIG. 22



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FIG. 21

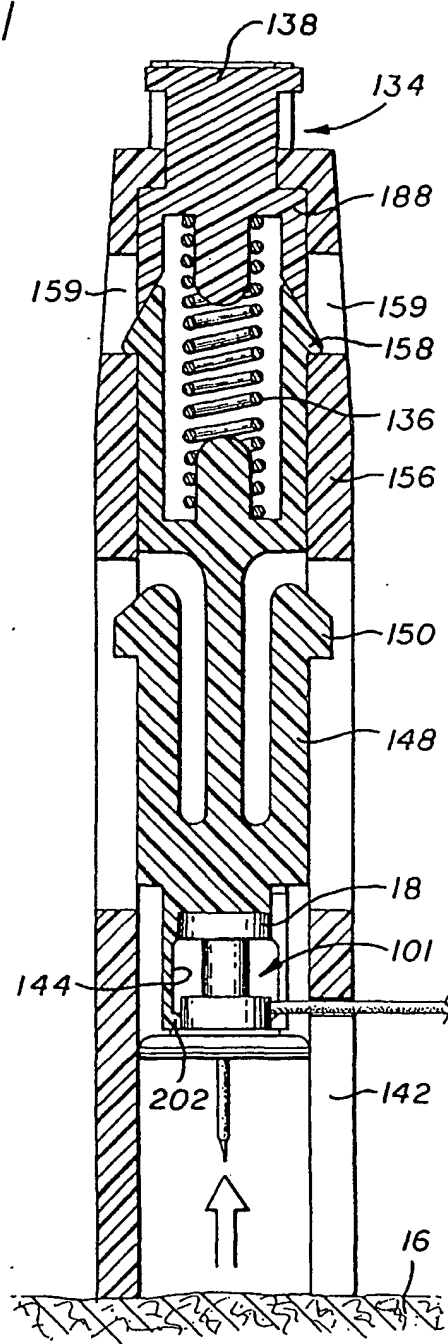
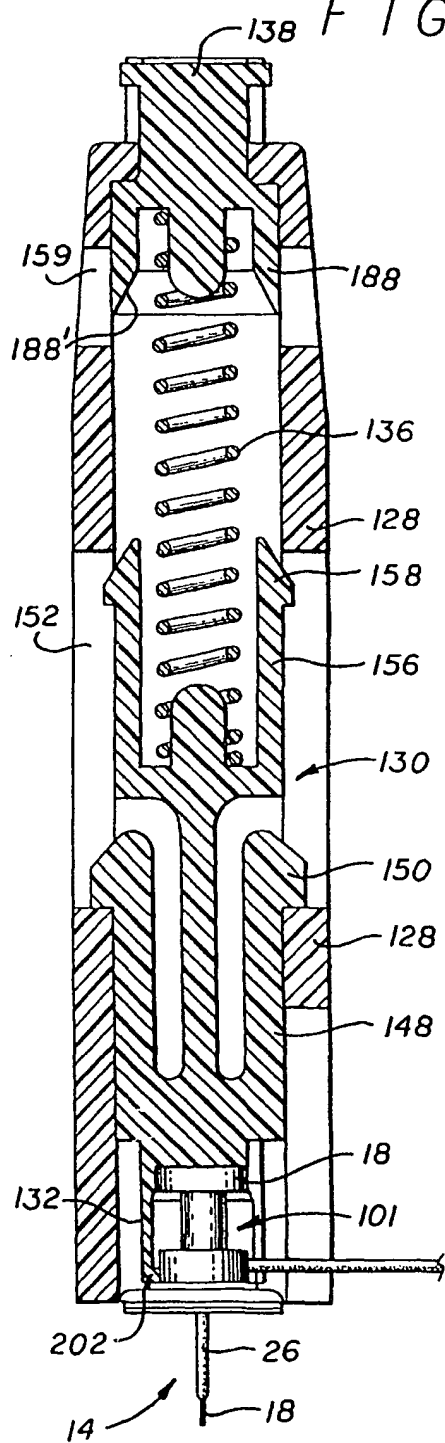


FIG. 23

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FIG. 25

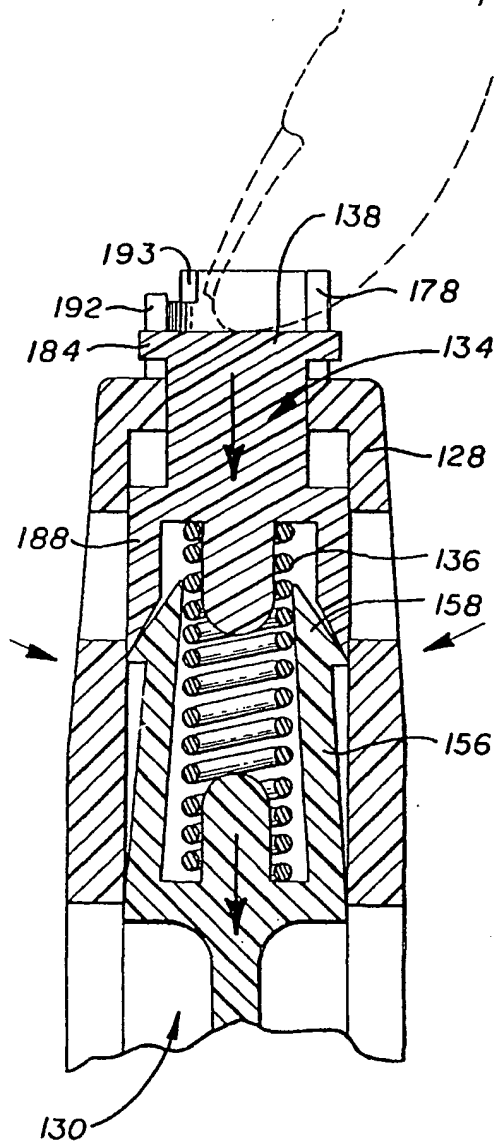
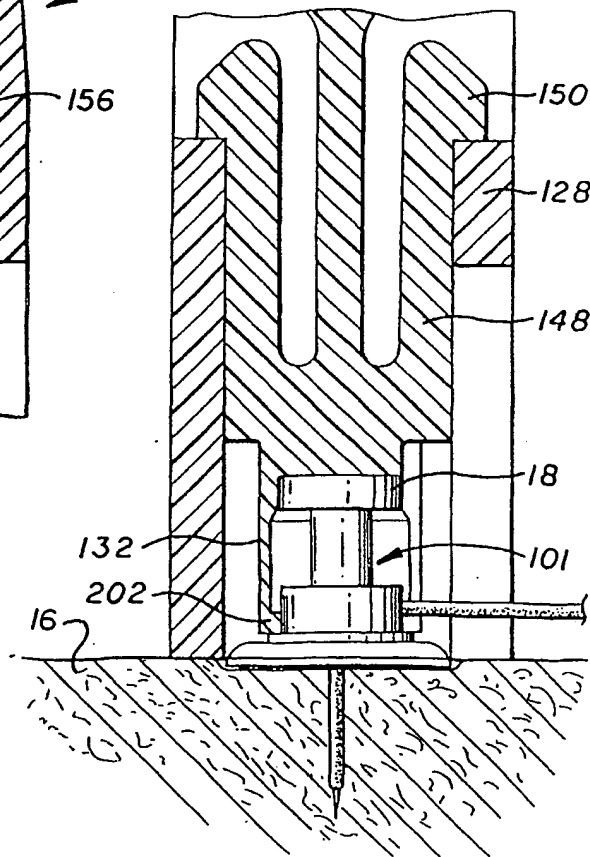
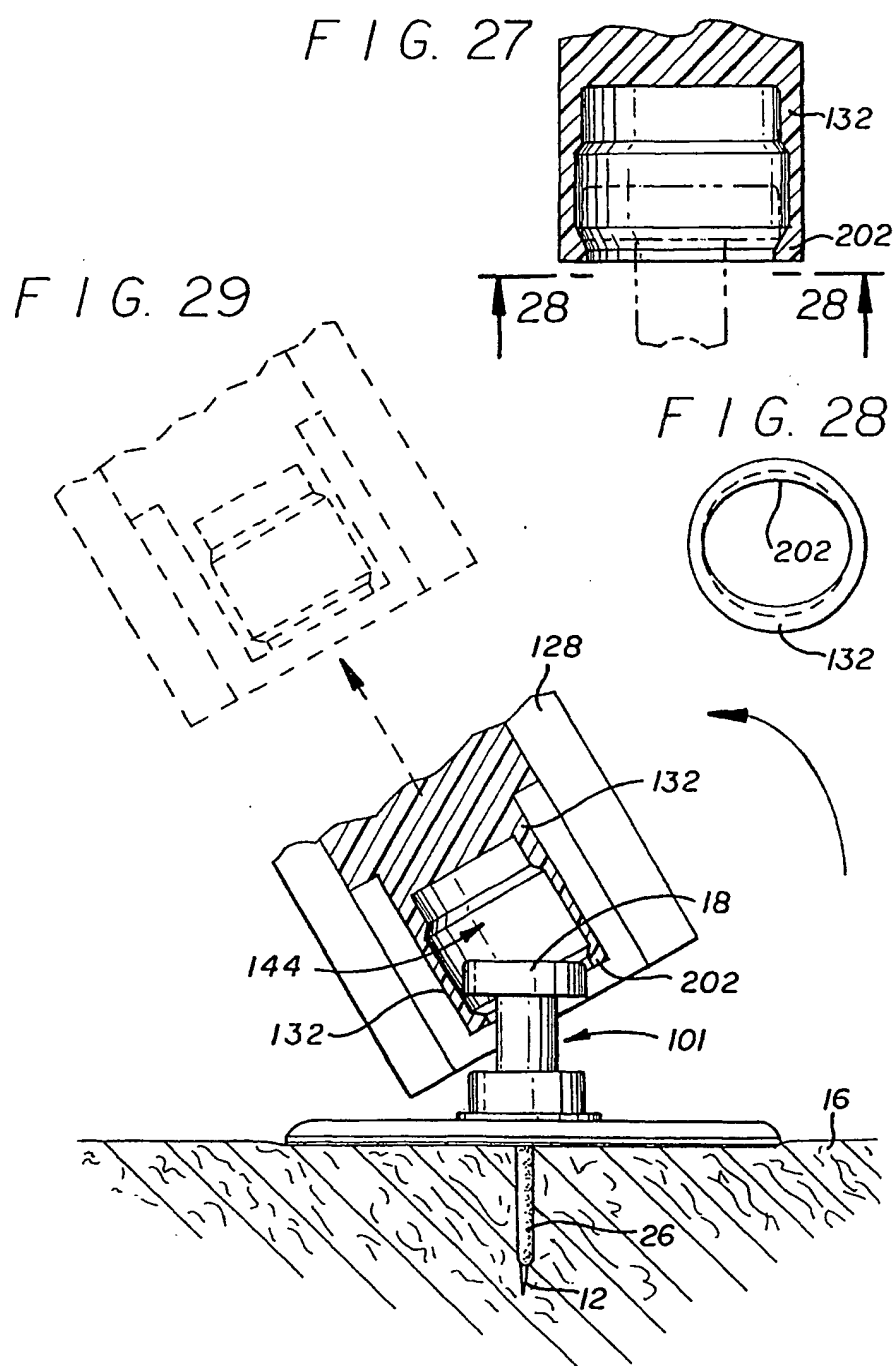


FIG. 26





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FIG. 30

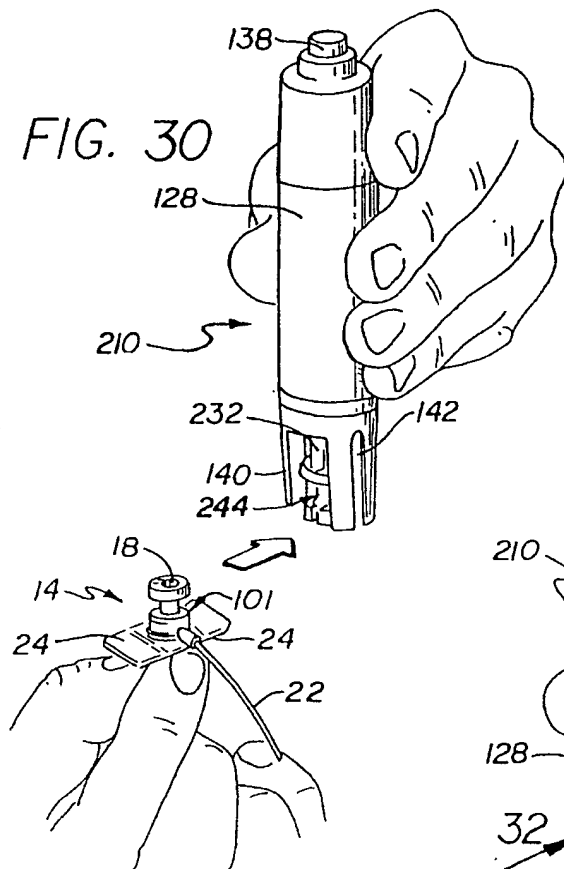


FIG. 31

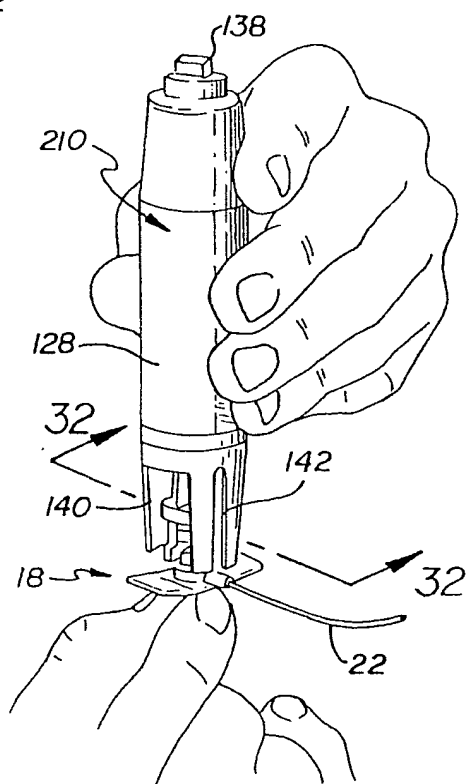
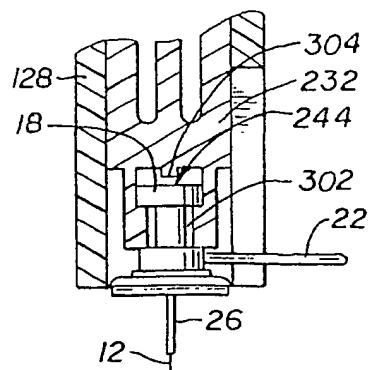


FIG. 32



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FIG. 33

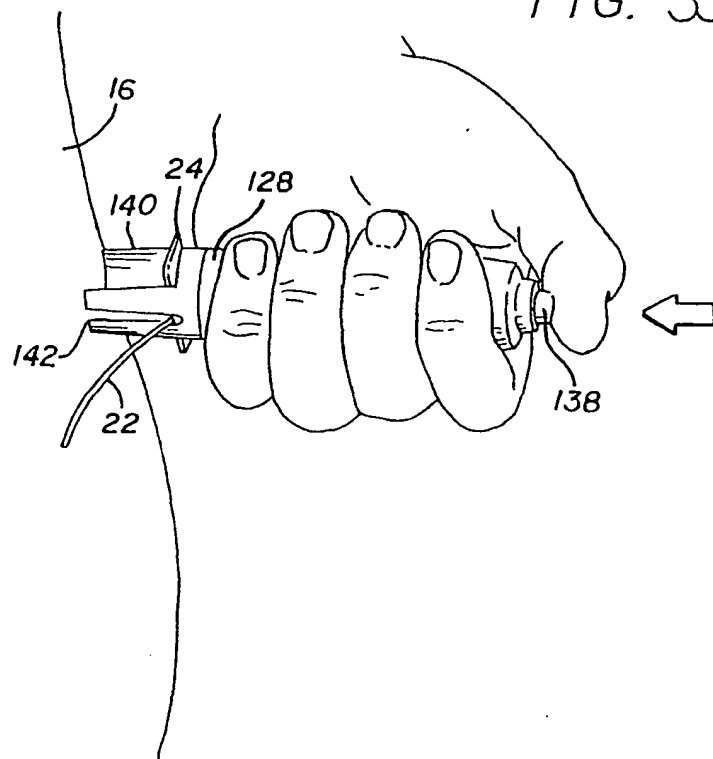
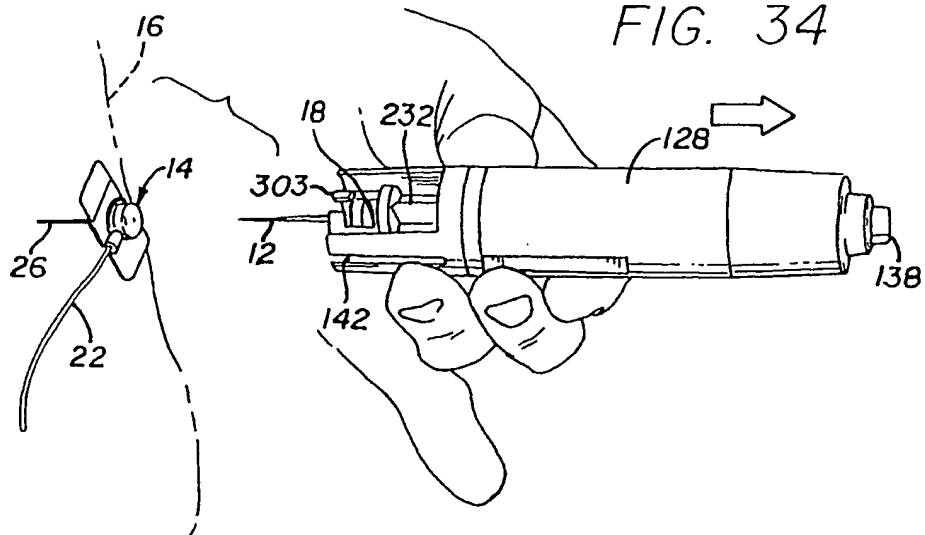
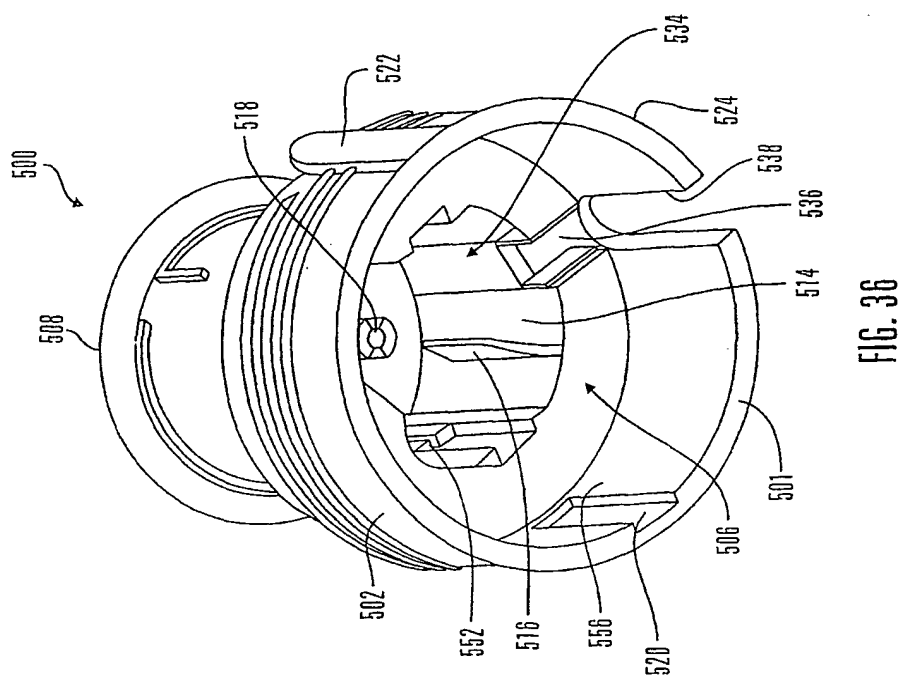
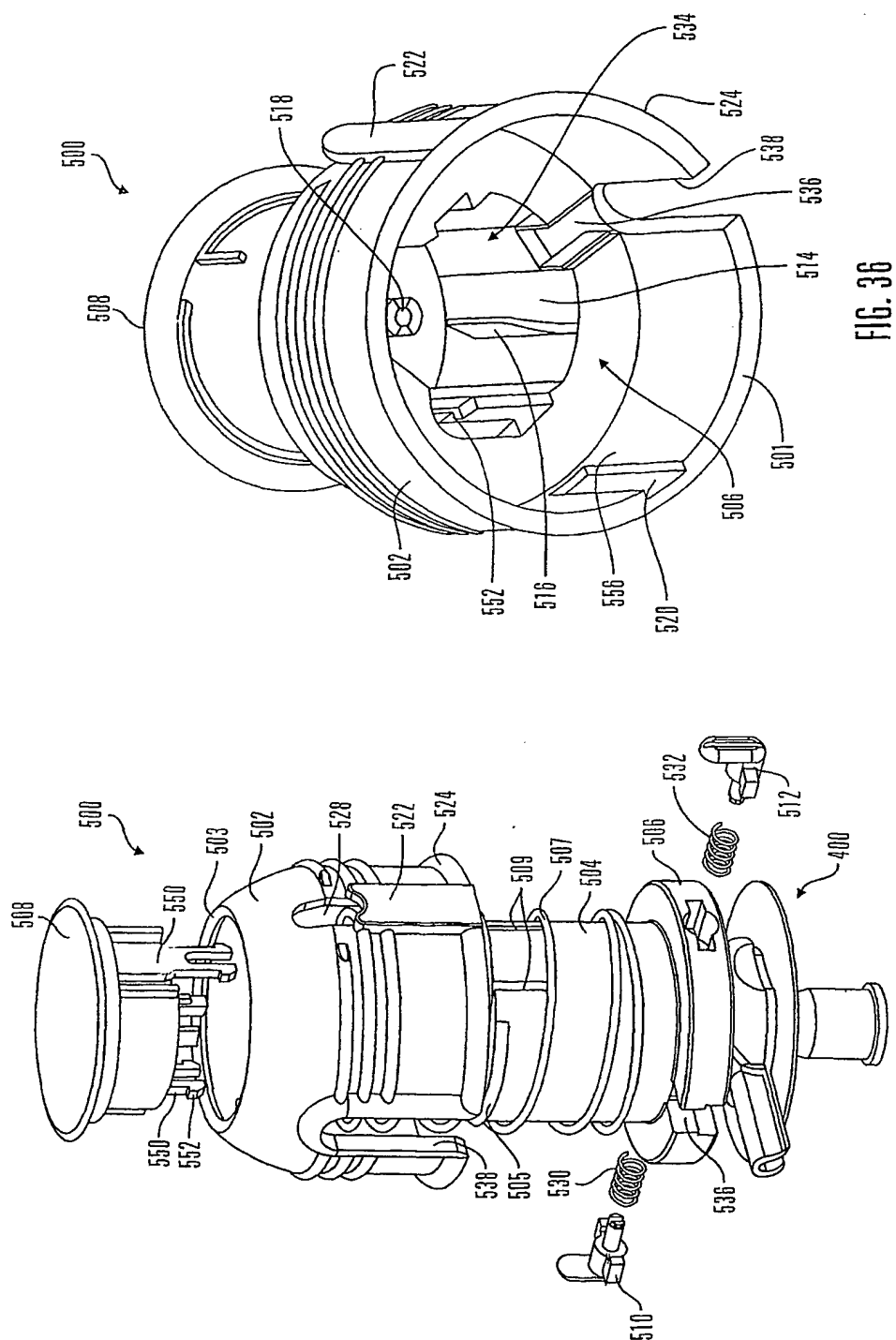


FIG. 34





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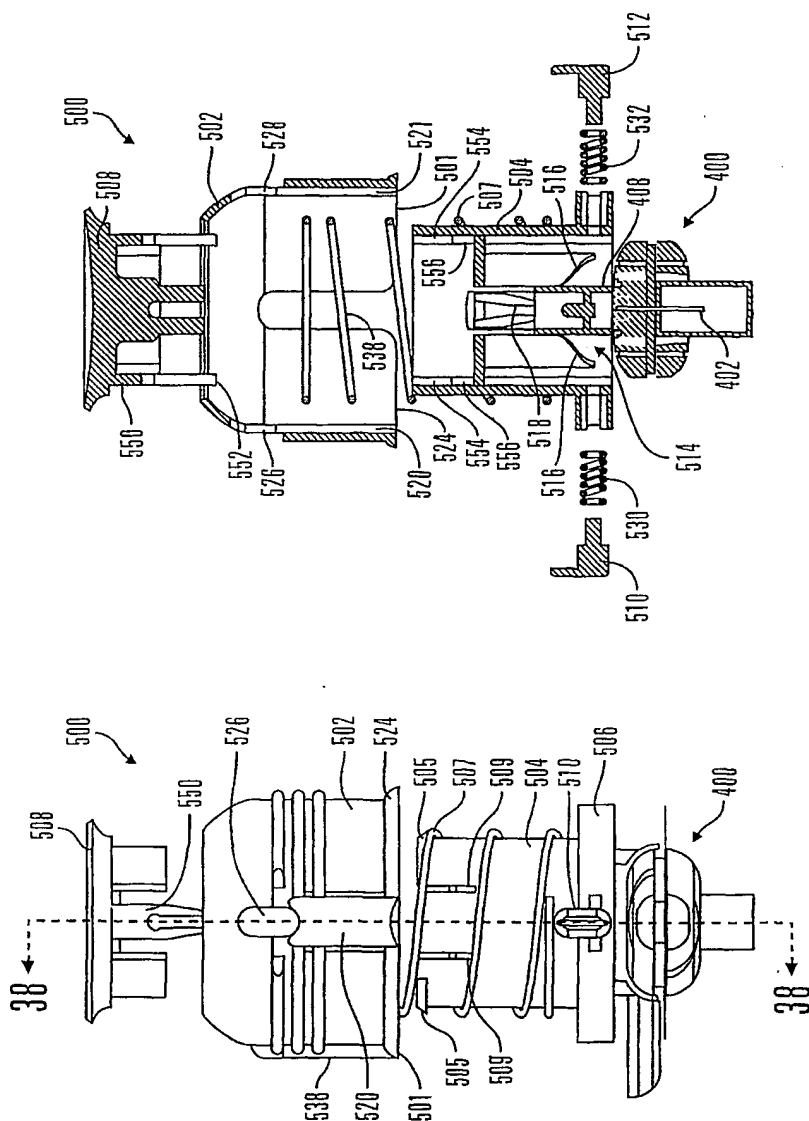


FIG. 38

FIG. 37

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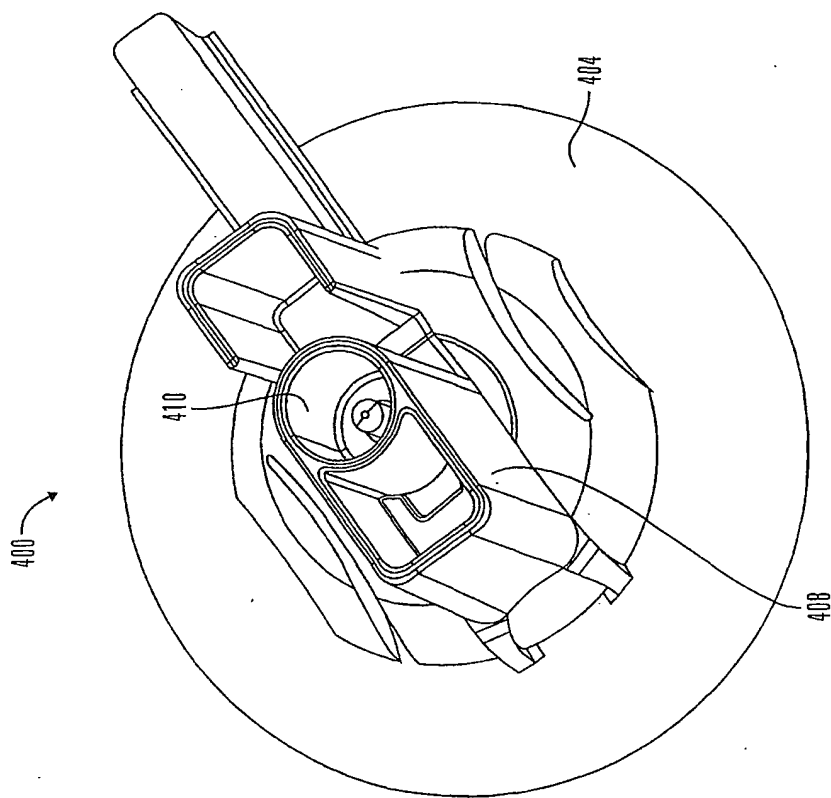


FIG. 39

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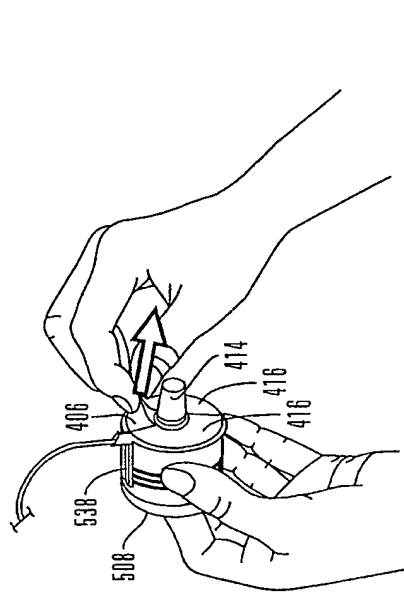


FIG. 40b

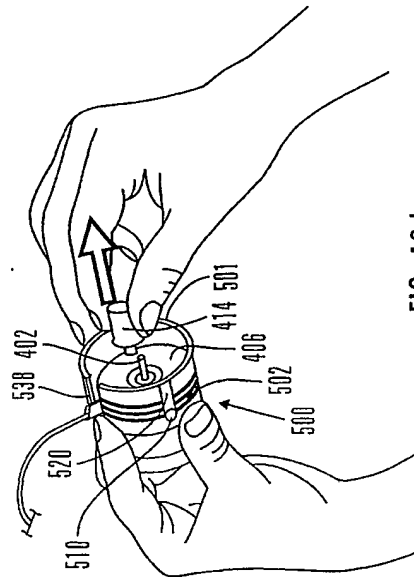


FIG. 40d

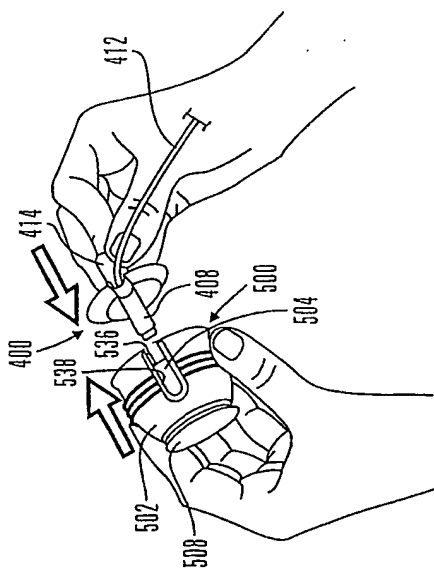


FIG. 40a

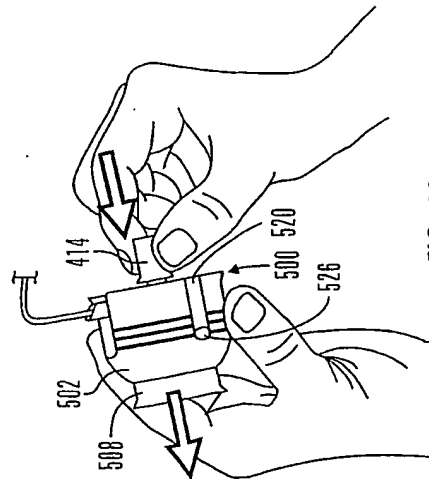
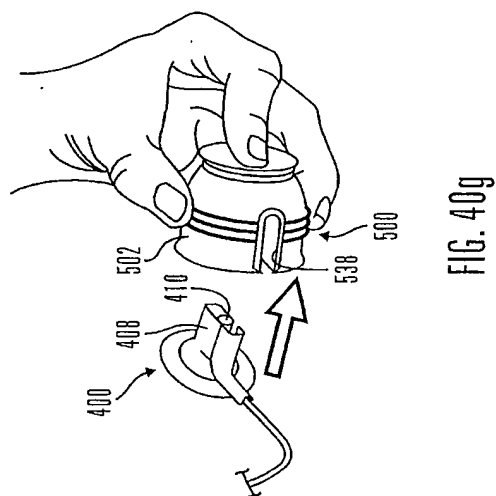
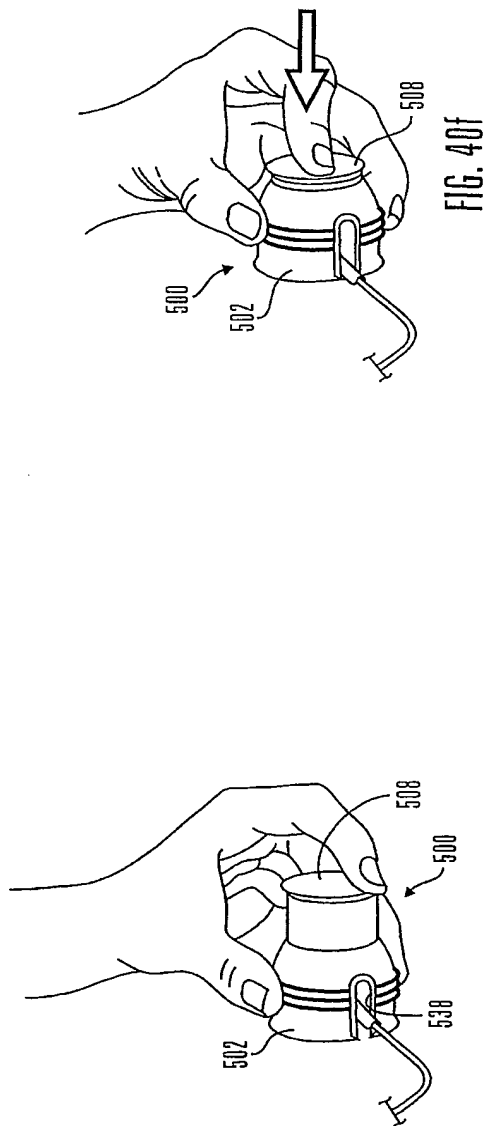


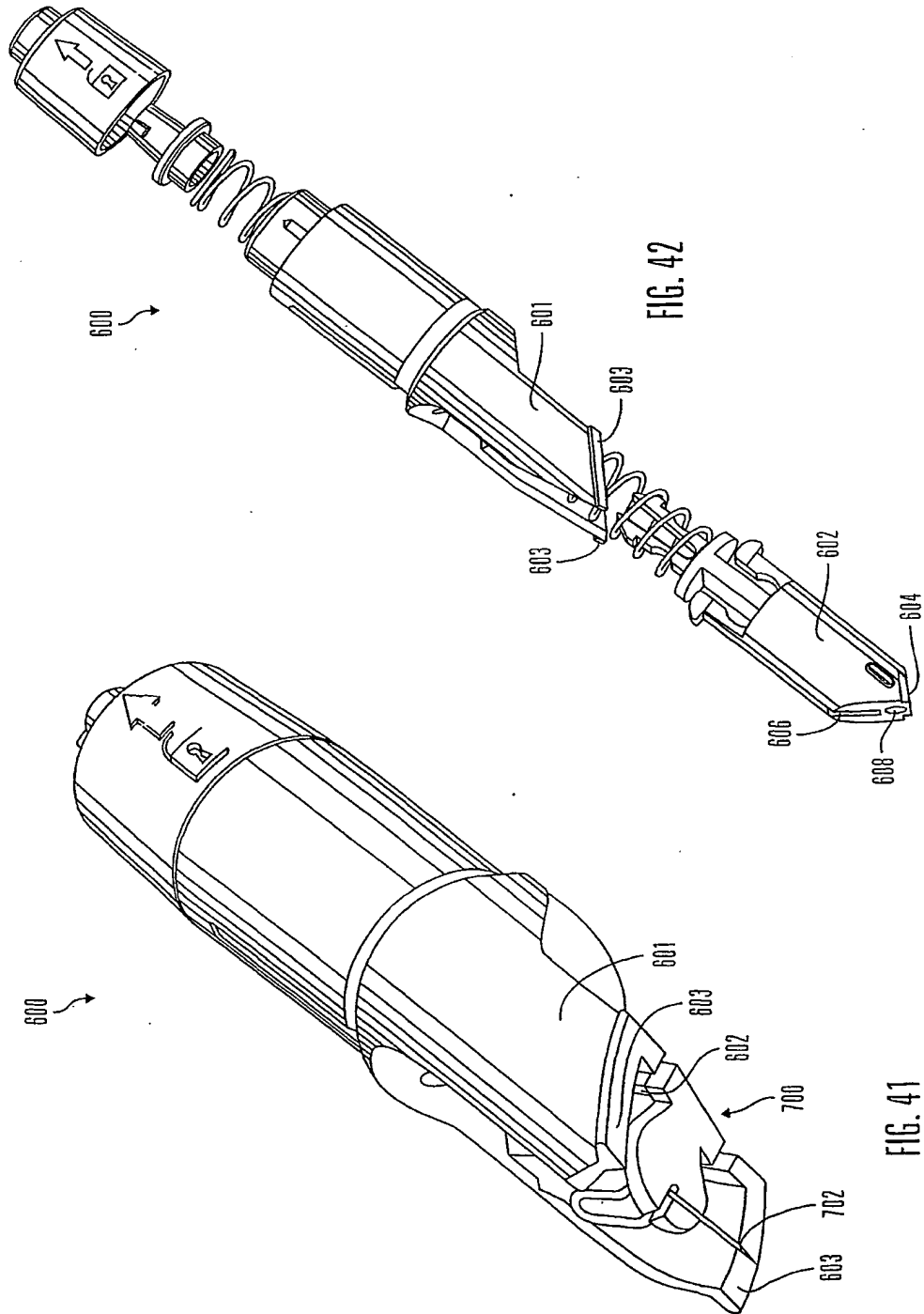
FIG. 40c

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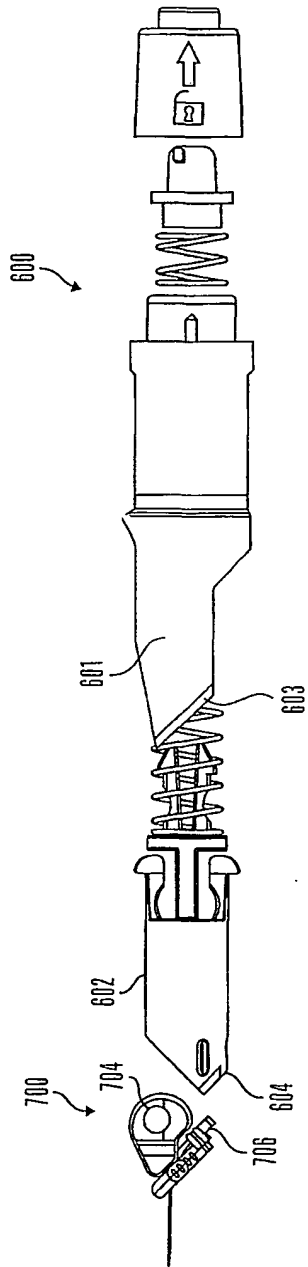


FIG. 43

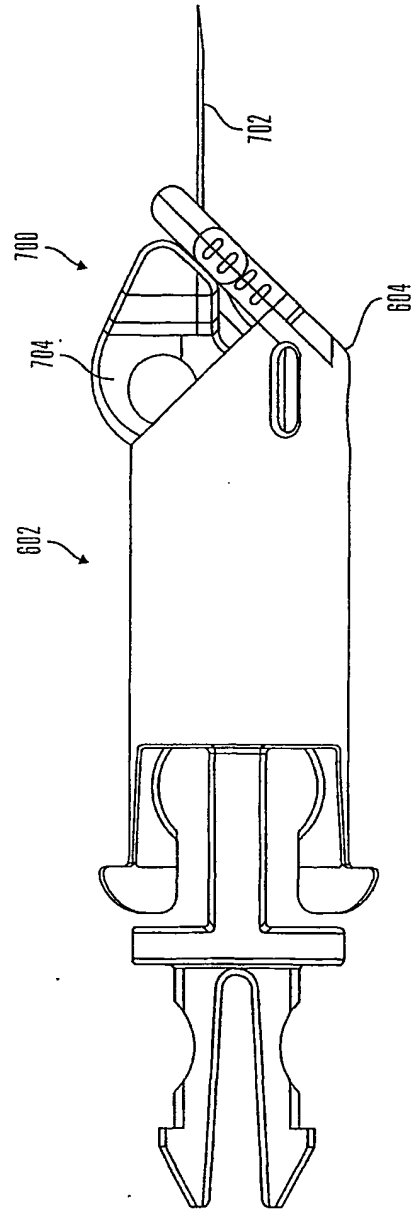
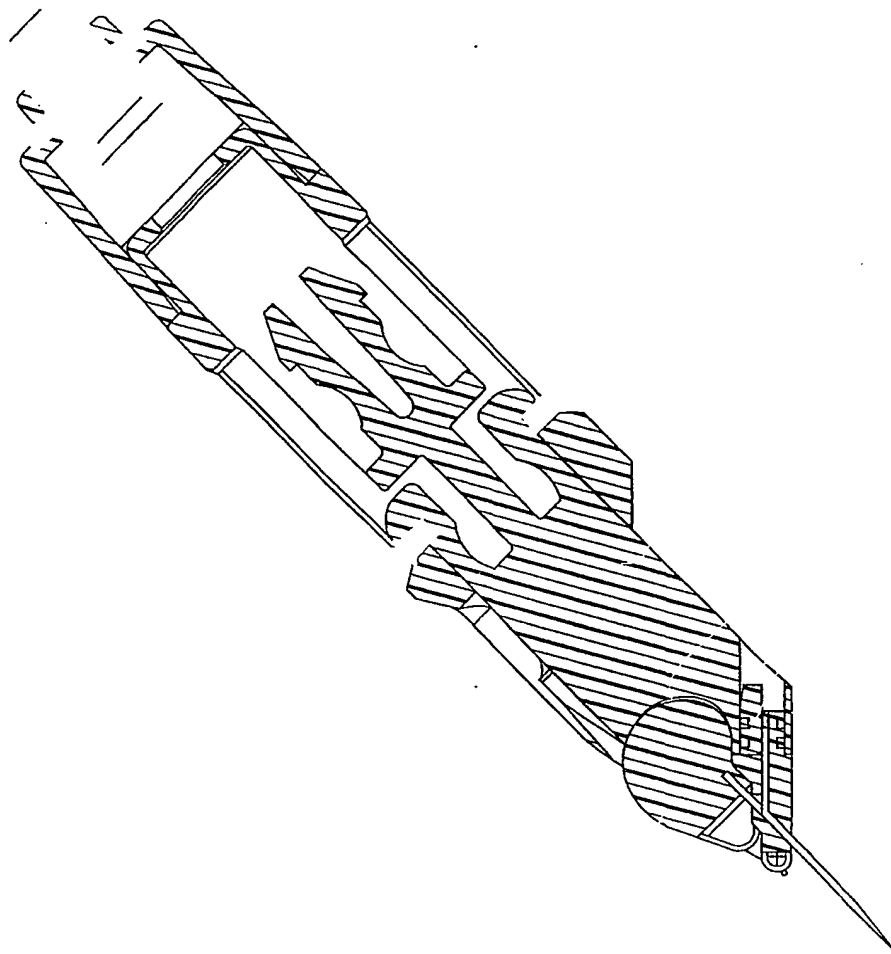


FIG. 44

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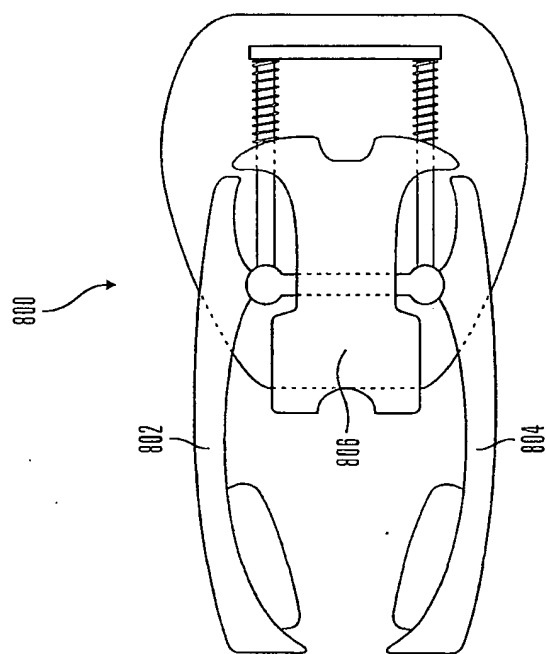


FIG. 47

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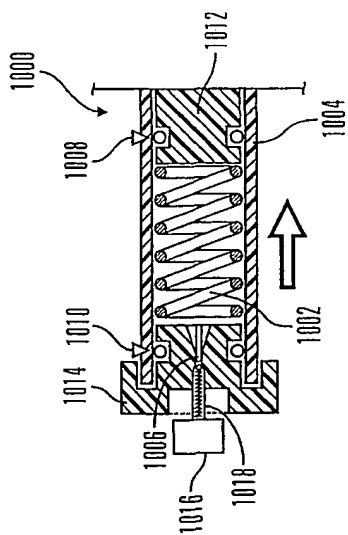


FIG. 48a

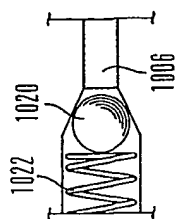


FIG. 48b

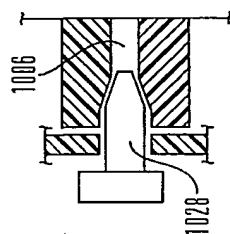


FIG. 48d

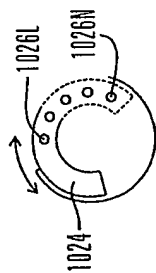


FIG. 48c

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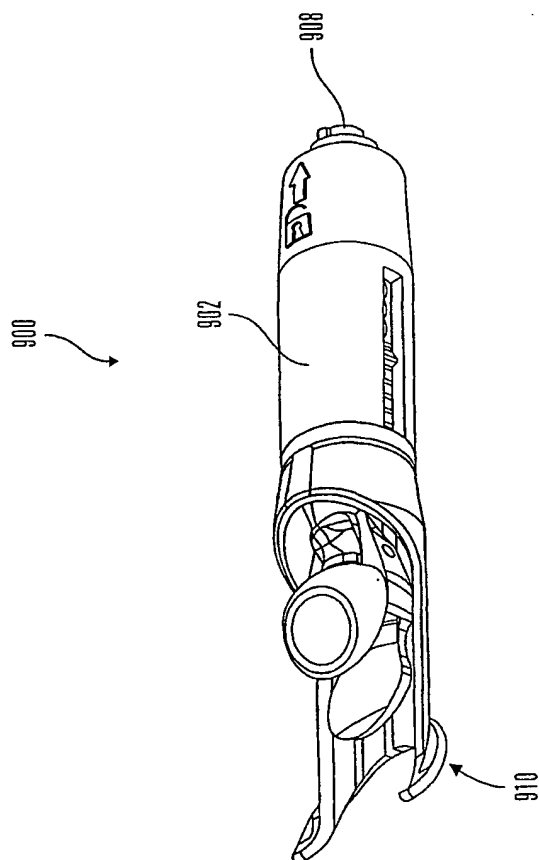
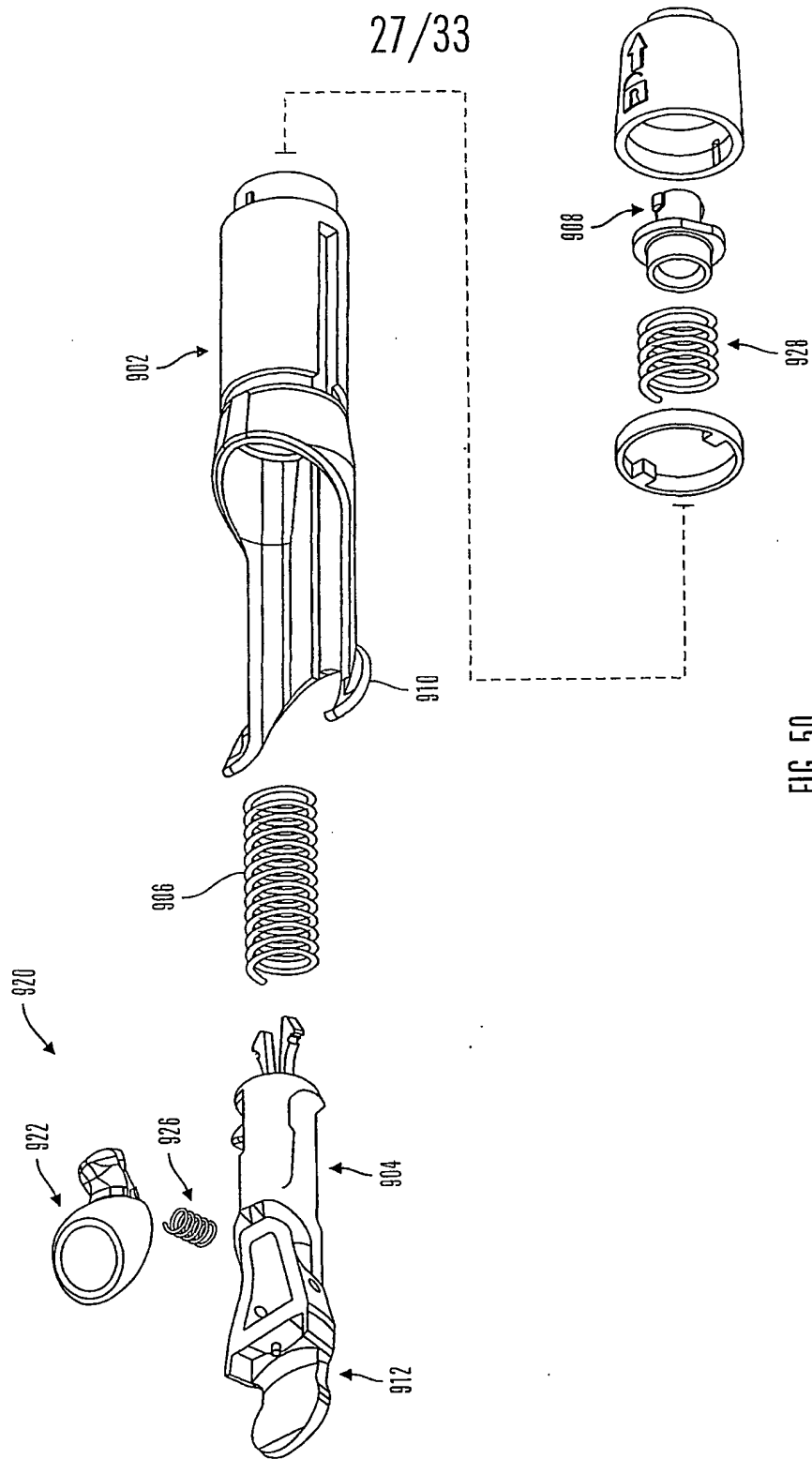


FIG. 49



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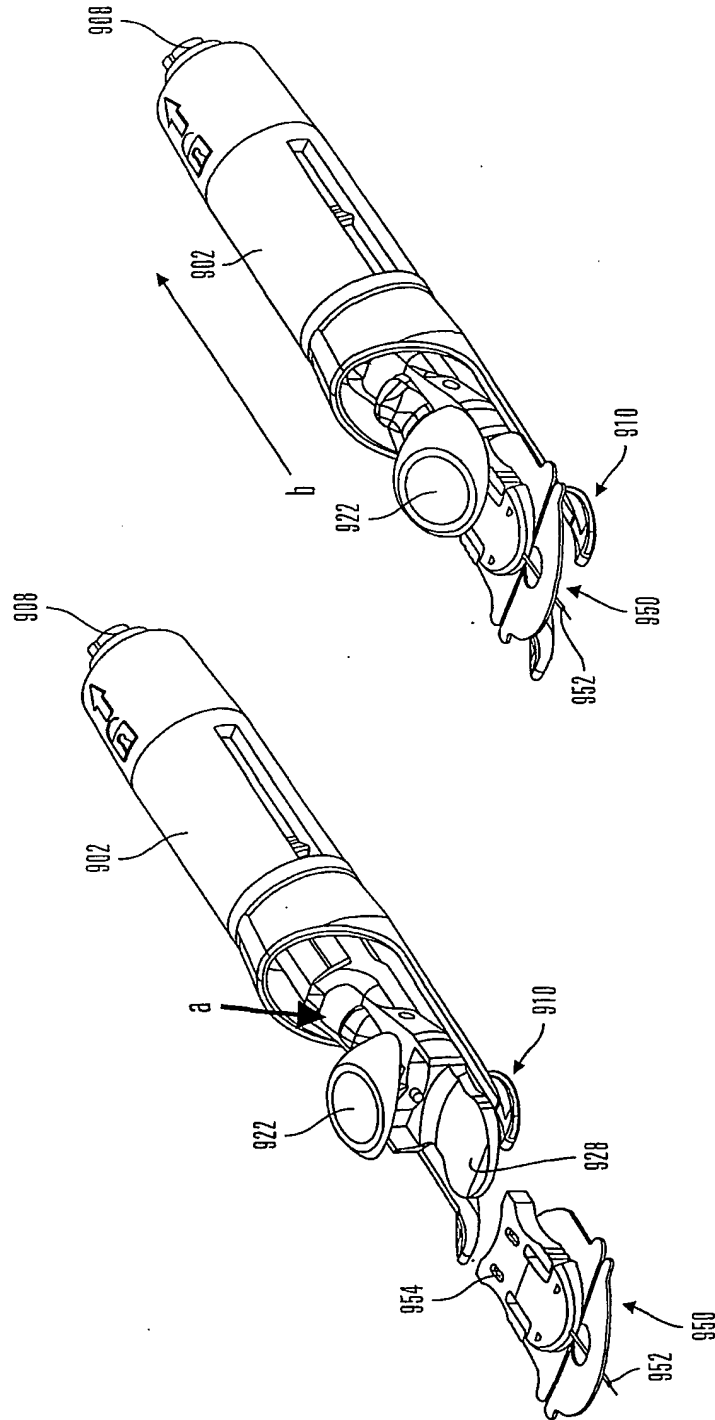


FIG. 51(b)

FIG. 51(a)



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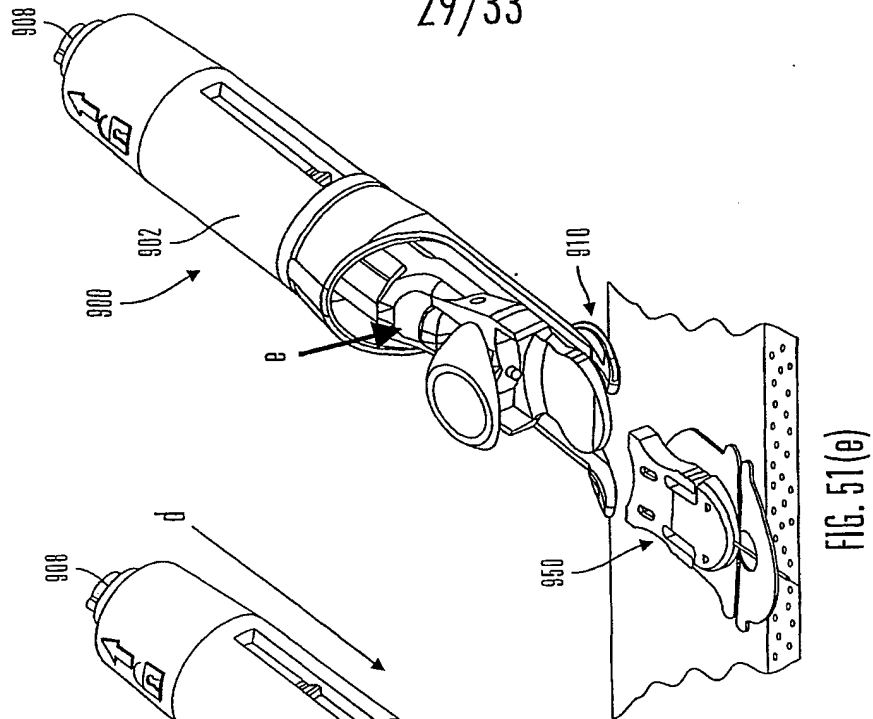


FIG. 51(e)

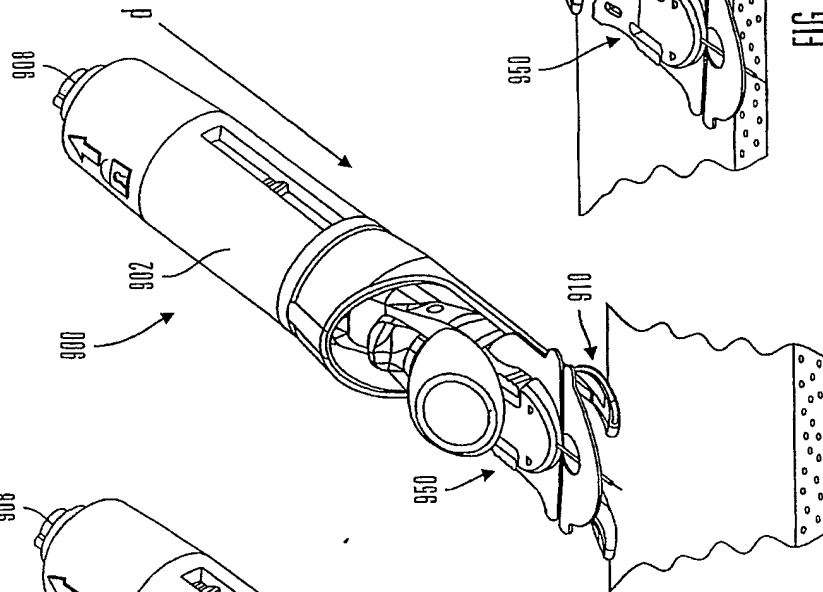


FIG. 51(d)

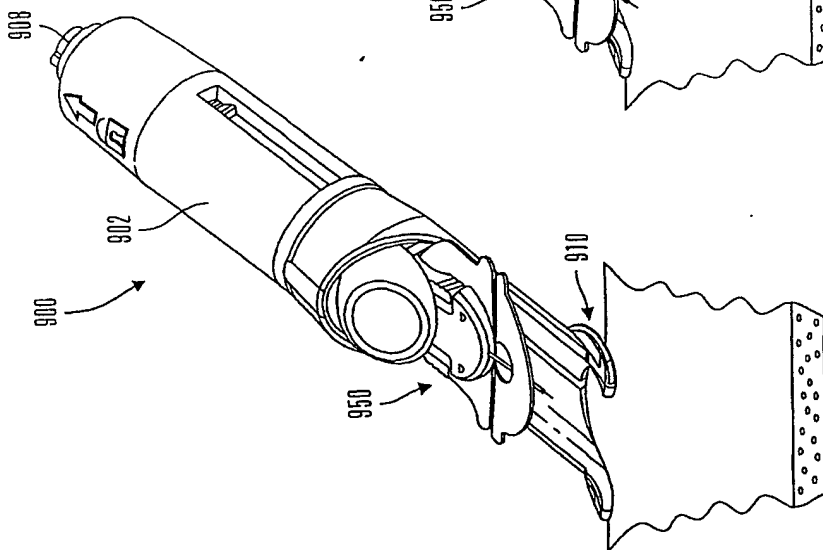
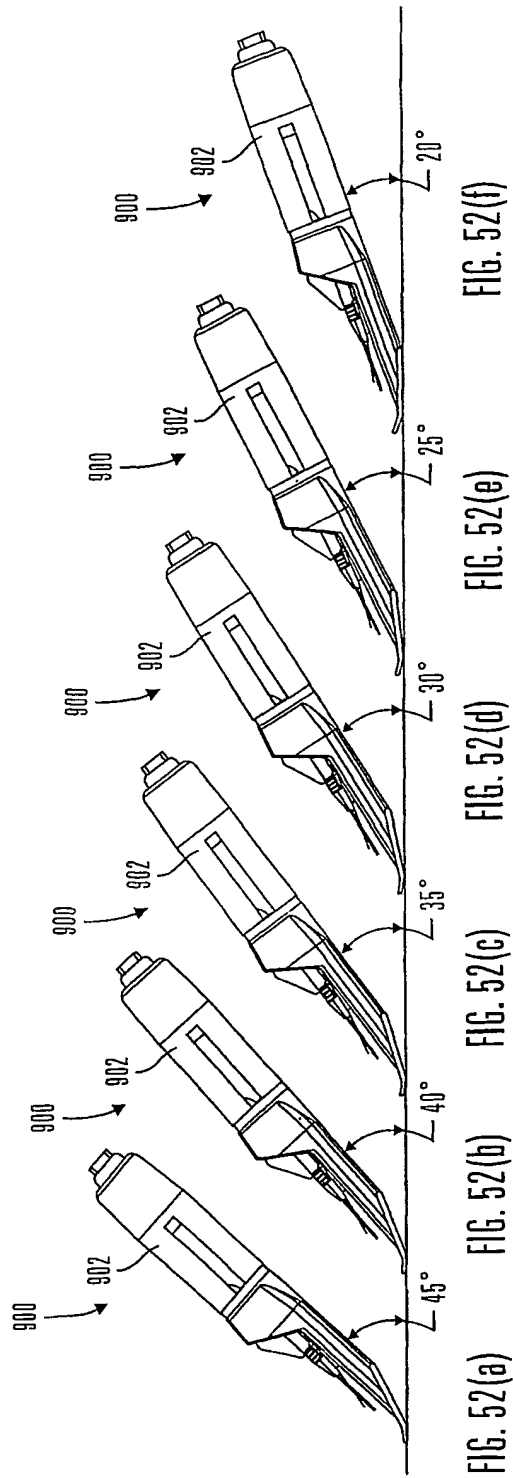


FIG. 51(c)

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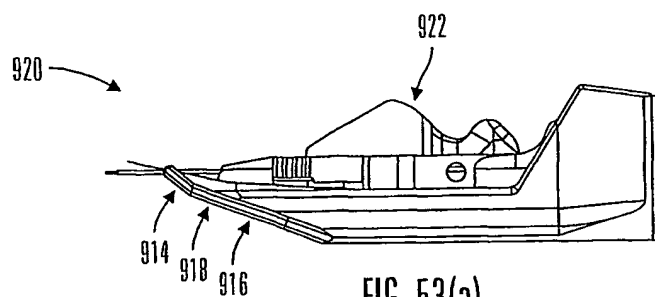


FIG. 53(a)

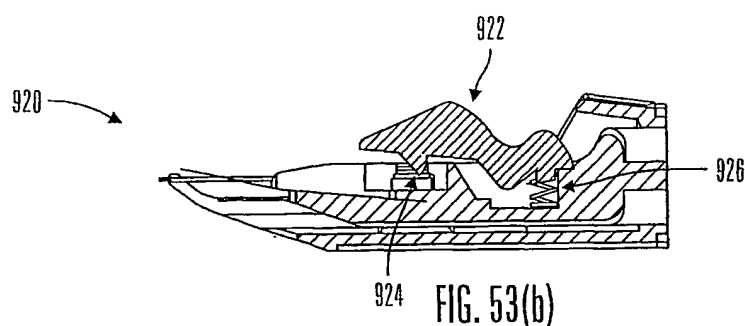


FIG. 53(b)

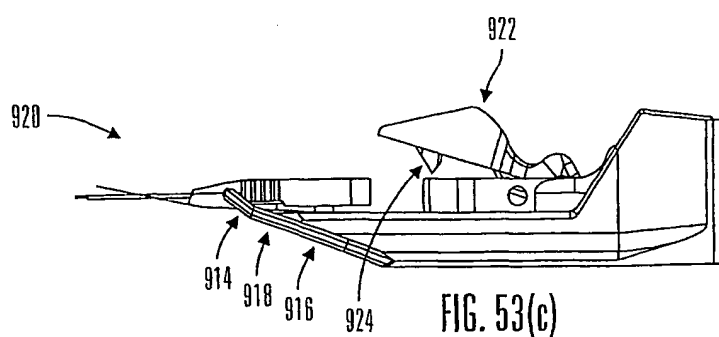


FIG. 53(c)

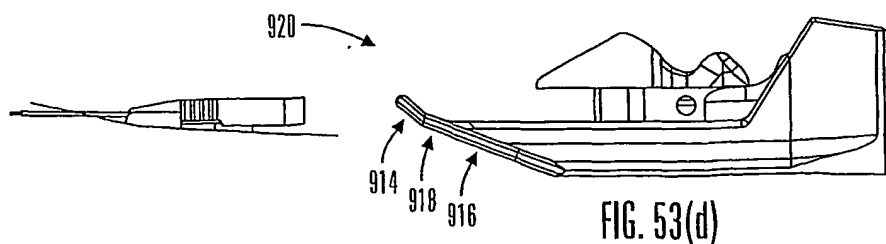
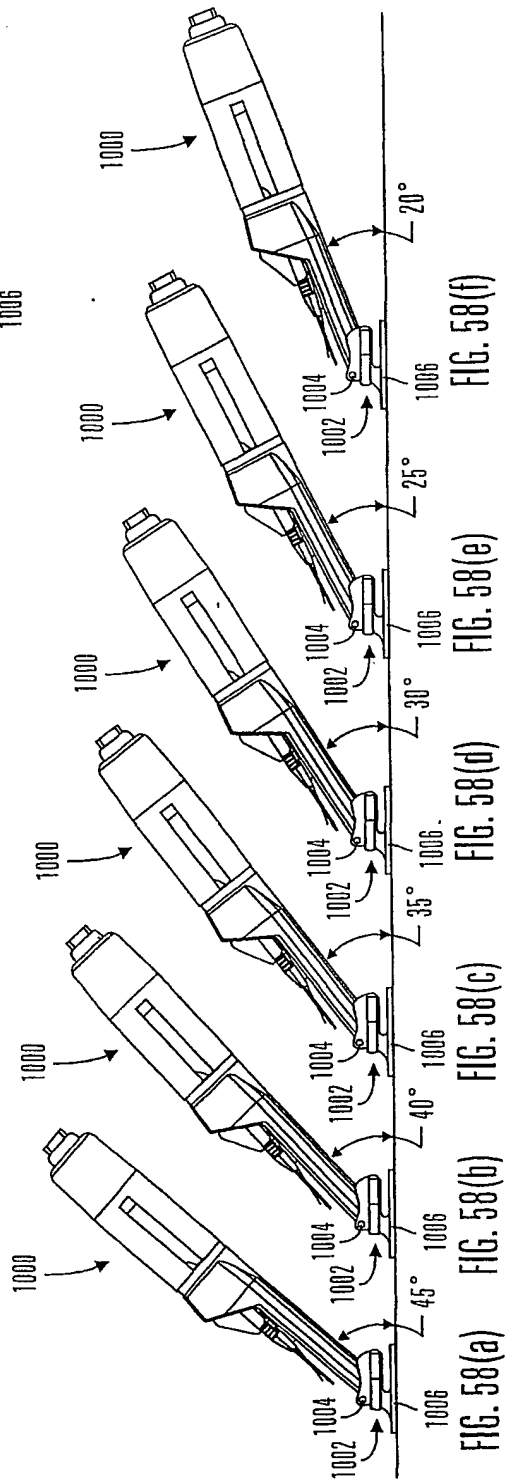
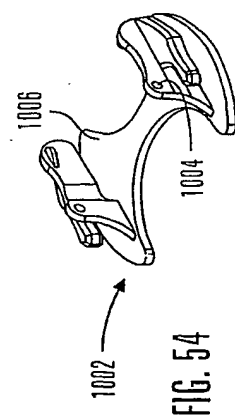
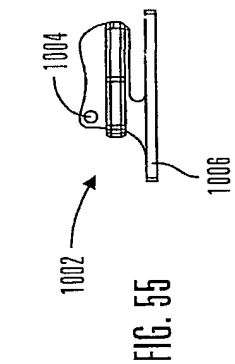
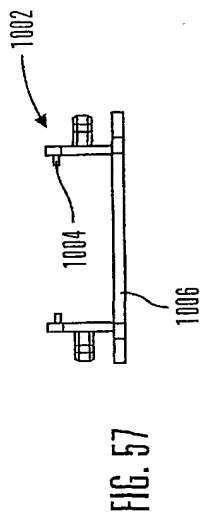
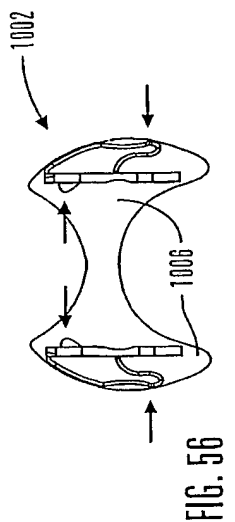


FIG. 53(d)

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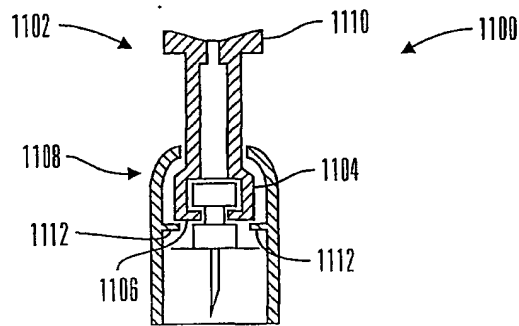


FIG. 59

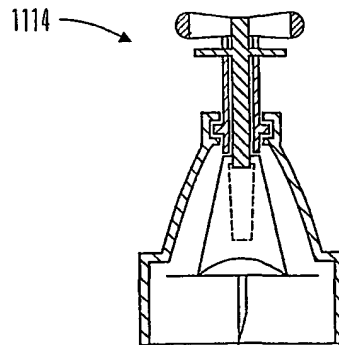


FIG. 60

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